Gabel
09/087871



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     FILE 'CAPLUS' ENTERED AT 14:46:09 ON 04 MAY 1999
L1          187 SEA ABB=ON  PLU=ON  (IMMUNOASSAY? OR IMMUN?(3A)ASSAY?)
                AND ((CLIN OR CLINICAL)(3A)(CHEMISTRY OR CHEM))
L2           70 SEA ABB=ON  PLU=ON  (IMMUNOASSAY? OR IMMUN?(3A)ASSAY?)(S)
                ((CLIN OR CLINICAL)(3A)(CHEMISTRY OR CHEM))
L3            0 SEA ABB=ON  PLU=ON  L2 AND PROCESSOR
L4            0 SEA ABB=ON  PLU=ON  L1 AND PROCESSOR
L5           28 SEA ABB=ON  PLU=ON  L1 AND DIAGNOS?
L6            1 SEA ABB=ON  PLU=ON  L1 AND ((BIO OR BIOL?)(W)CHEM? OR
                BIOCHEM?)(S)MARKER
L7           29 SEA ABB=ON  PLU=ON  L5 OR L6

=> d 1-29 .beverly

L7   ANSWER 1 OF 29  CAPLUS  COPYRIGHT 1999 ACS
ACCESSION NUMBER:        1998:440008  CAPLUS
DOCUMENT NUMBER:         129:172679
TITLE:                   Development of a rapid microparticle-enhanced
                         turbidimetric immunoassay for plasma
                         fatty acid-binding protein, an early marker of
                         acute myocardial infraction
AUTHOR(S):               Robers, Markus; Van Der Hulst, Ferenc F.;
                         Fischer, Marc A. J. G.; Roos, Werner; Salud,
                         Carlos E.; Eisenwiener, Hans-Georg; Glatz, Jan
                         F. C.
CORPORATE SOURCE:        Department of Physiology, Cardiovascular
                         Research Institute, Maastricht (CARIM),
                         Maastricht University, Neth.
SOURCE:                  Clin. Chem. (Washington, D. C.) (1998), 44(7),
                         1564-1567
                         CODEN: CLCHAU; ISSN: 0009-9147
PUBLISHER:               American Association for Clinical Chemistry
DOCUMENT TYPE:           Journal
LANGUAGE:                English
AB   Teh simplicity, reproducibility, and full automation in a widely
     used clin. chem. analyzer like the COBAS MIRA
     seem to be factors of choice for the FABP latex immunoassay
     for routine clin. diagnosis of acute myocardial
     infarction.

L7   ANSWER 2 OF 29  CAPLUS  COPYRIGHT 1999 ACS
ACCESSION NUMBER:        1998:161226  CAPLUS
DOCUMENT NUMBER:         128:177719
TITLE:                   Future perspectives of biotechnology in clinic
                       diagnostics. Part 1. Immunological
                         methods and PCR
AUTHOR(S):               Brandt, Burkhard Hermann
CORPORATE SOURCE:        Inst. Klinische Chem. Laboratoriumsmedizin,
                         Univ. Muenster, Muenster, D-48149, Germany
                              Searcher  :  Shears   308-4994
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SOURCE: Bioforum (1998), 21(1/2), 14-16
CODEN: BFRME3; ISSN: 0940-0079
PUBLISHER: GIT Verlag GmbH
DOCUMENT TYPE: Journal; General Review
LANGUAGE: German

AB A review with 4 refs. is given on the development of biotechnol. in clin. **diagnosis**. The ultrasensitive polymerase chain reaction (PCR) method opened new fields of **diagnostics**. The direct measurement of the vial load in patients blood improved the monitoring and treatment of hepatitis and HIV infections. Similar improvements are expected from the detection of disseminated tumor cells in the peripheral blood, urine, or feces. The detection of those cells will be of addnl. value for clin. staging of the disease and for the early detection of metastasis. New PCR- and sequencing methods will allow the identification of gene carriers of familiar cancer syndromes, of gene mutations predisposing for thrombosis and genetic defects of lipid metab. The prolongation of transplants lifetime due to a more precise HLA typing will also be achieved by the new mol. biol. methods.

L7 ANSWER 3 OF 29 CAPLUS COPYRIGHT 1999 ACS

ACCESSION NUMBER: 1998:52937 CAPLUS
DOCUMENT NUMBER: 128:164617
TITLE: Application of magnetic particles in **immunoassays**
AUTHOR(S): Meza, Mary
CORPORATE SOURCE: Bangs Lab., Inc., Fishers, IN, 46038-2886, USA
SOURCE: Sci. Clin. Appl. Magn. Carriers, Proc. Int. Conf., 1st (1997), Meeting Date 1996, 303-309. Editor(s): Haefeli, Urs. Plenum: New York, N. Y.
CODEN: 65MWAX
DOCUMENT TYPE: Conference
LANGUAGE: English

AB For many years, the immunol. antibody-antigen interaction has been used to det. concns. of analytes useful in medical **diagnostics**. Antibody or antigen is typically immobilized onto a solid phase, which traditionally has included filters, tubes, wells or plastic beads. The use of small magnetic particles as the solid phase ahs revolutionized the field of **clin. chem**. by facilitating the development of more sensitive higher-throughput automated **immunoassays**. Many of today's automated **immunoassay** systems rely on magnetic sepn. It should be clarified that the particles used in these **immunoassays** are not truly magnetic, but are instead superparamagnetic. They respond to a magnetic field, but retain no magnetic particles when the field is removed. This lack of magnetic remanence enables the beads to be magnetically concd. and redispersed repeatedly during an **immunoassay**, without ever

forming magnetized clumps of particles. The overwhelming majority of **immunoassays** are based on two basic assay formats: the two-site, or sandwich assay and the competitive binding assay. There are, of course, variations on these two basis themes, but for simplicity's sake, only these two formats are discussed.

L7 ANSWER 4 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1997:706474 CAPLUS
DOCUMENT NUMBER: 128:31162
TITLE: Development and analytical performance of an automated screening method for cannabinoids on the Dimension **clinical chemistry** system
AUTHOR(S): Obzansky, D. M.; Gorman, E. G.; Kramer, S. P.; Masulli, I. S.; Nuzzaci, E. A.; Skogen, W. F.
CORPORATE SOURCE: Dade Chemistry Systems Inc., Newark, DE, 19714, USA
SOURCE: J. Autom. Chem. (1997), 19(5), 169-173
CODEN: JAUCD6; ISSN: 0142-0453
PUBLISHER: Taylor & Francis
DOCUMENT TYPE: Journal
LANGUAGE: English
AB A.fully automated, random access method for the detn. of cannabinoids (UTHC) was developed for the Dimension AR and XL **clin. chem.** systems. The method utilizes Abuscreen ONLINE reagents and a multianalyte liq. calibrator contg. 11-nor-.DELTA.9-THC-9-carboxylic acid. Within-run and total reproducibility, detd. using NCCLS protocol EP5-T2, was less than 0.6% and 1.6% CV, resp., at all concns. Calibration stability was retained for at least 30 days. An extensive evaluation of non-structurally related drugs and various physiol. substances indicated lack of interference in the method. No sample carry-over was obsd. following a specimen contg. 1886 ng/mL 11-nor-.DELTA.9-THC-9-carboxylic acid. A 99.1% agreement (N = 445 samples) was found between an EMIT based method on the aca discrete clin. analyzer and the Dimension UTHC method. Dimension **clin. chem.** system and aca discrete clin. analyzer are registered trademarks of Dade International.

L7 ANSWER 5 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1997:585272 CAPLUS
DOCUMENT NUMBER: 127:274963
TITLE: An assessment of **clinical chemistry** index in diabetes mellitus (DM) with early nephropathy
AUTHOR(S): Zhu, Lihua; Liu, Jingxia; Hong, Jianmei
CORPORATE SOURCE: Dep. Medical Lab. Sci., First Hospital, Beijing Medical Univ., Beijing, 100034, Peop. Rep. China
SOURCE: Beijing Yike Daxue Xuebao (1997), 29(2), 176-177

CODEN: BYDXEV; ISSN: 1000-1530
PUBLISHER: Beijing Yike Daxue
DOCUMENT TYPE: Journal
LANGUAGE: Chinese

AB The urinary microalbumin (mAlb), N-acetyl-beta-D-glucosaminidase (NAG) and serum IV collagen (IV-C)'s value in the patients with early nephropathy of diabetes mellitus was assessed in 206 cases of clin. patients with diabetes mellitus **diagnosed** by WHO criterion. Random urine samples were detd. for mAlb by immunoturbidimetric method, for NAG by p-nitrophenol-glucoside method, and for serum IV-C samples by ELISA method. The more serious the renal damage was, the better the correlation between mAlb and NAG became. There were 35.3% and 27.7% pos. rates of mAlb and NAG in DM patients with neg. protein urine and neg. mAlb urine resp. The mean value of IV-c in DM patients was higher than that of the normal range. The results suggest that mAlb and NAG are 2 sensitive indexes for early renal injury, combine the both markers, early renal damage of 47.4% of clin. DM patients without urine protein was found.

L7 ANSWER 6 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1997:378484 CAPLUS
DOCUMENT NUMBER: 127:60761
TITLE: Evaluation of a new chemiluminescence system for the study of thyroid function
AUTHOR(S): Pinto Sierra, I.; Enguix Armada, A.
CORPORATE SOURCE: Servicio Analisis Clinicos, Hospital Carmen Severo Ochoa, Cangas del Narcea, Spain
SOURCE: Rev. Soc. Esp. Bioquim. Clin. Patol. Mol. (1997), 16(1), 19-22
CODEN: RSQCFW
PUBLISHER: Ediciones Mayo
DOCUMENT TYPE: Journal
LANGUAGE: Spanish

AB We evaluated a new chemiluminescence technique in testing thyroid function (TSH and free thyroxine). The evaluation was carried out following the recommendations of the Sociedad Espanola de Bioquimica Clinica y Patologia Mol. (SEQC) and the International Federation of **Clin. Chem.** (IFFCC). The Access.RTM. system (Sanofi Pasteur **Diagnostics**) is based on a two-site sandwich enzyme **immunoassay** for TSH and on a two-step competitive procedure for free thyroxine. Access.RTM. system uses a paramagnetic solid phase to sep. the bound analyte. The chemiluminescent substrate is dioxetane phosphate. The within-run CV was 4.66% for 0.49 mUI/L of TSH and 13.7% for 6.66 pmol/L of free thyroxine; between-run CV was 3.76% for 0.51 mUI/L of TSH and 11.5% for 6.38 pmol/L of free thyroxine. The range of linearity for free thyroxine was 0-67 pmol/L. The lower detection limit for TSH was 0.0026mUI/L. Access.RTM. automated **immunoassays** offer

good reliability, practicability and performance characteristics and it is suitable for testing thyroid function.

L7 ANSWER 7 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1997:26743 CAPLUS
DOCUMENT NUMBER: 126:139964
TITLE: Evaluation of urinary metanephrine and normetanephrine enzyme **immunoassay** (ELISA) kits by comparison with isotope dilution mass spectrometry
AUTHOR(S): Wolthers, Bert G.; Kema, Ido P.; Volmer, Marcel; Wesemann, Reinhard; Westermann, Juergen; Manz, Bernhard
CORPORATE SOURCE: Cent. Lab. Clin. Chem., Univ. Hosp., Groningen, 9700 RB, Neth.
SOURCE: Clin. Chem. (Washington, D. C.) (1997), 43(1), 114-120
CODEN: CLCHAU; ISSN: 0009-9147
PUBLISHER: American Association for Clinical Chemistry
DOCUMENT TYPE: Journal
LANGUAGE: English
AB Detn. of urinary 3-O-methylated catecholamines (metanephrines) is generally considered a principal test for the **clin. chem. diagnosis** of pheochromocytoma and is currently performed predominantly with chromatog. techniques such as gas chromatog. and HPLC. Enzyme **immunoassays** based on microtiter plate technol. have recently been developed for the quant. detn. of urinary metanephrine (M) and normetanephrine (NM). We compared the results for urinary M and NM detd. by these ELISA methods with those obtained by a recently developed isotope diln. mass spectrometric method. From this comparative study we can conclude that the investigated ELISA methods are applicable in the quantification of urinary M and thus can be successfully used to establish the **diagnosis** of pheochromocytoma. These relatively simple methods can be executed in any clin. lab. and in time may replace the present, more complicated, chromatog. techniques.

L7 ANSWER 8 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1996:696703 CAPLUS
DOCUMENT NUMBER: 126:5893
TITLE: Understanding clinical immunological testing in alleged chemically induced environmental illnesses
AUTHOR(S): Salvaggio, John E.
CORPORATE SOURCE: Medical Center, Tulane University, New Orleans, LA, 70112-2699, USA
SOURCE: Regul. Toxicol. Pharmacol. (1996), 24(1, Pt. 2), S16-S27

CODEN: RTOPDW; ISSN: 0273-2300
PUBLISHER: Academic
DOCUMENT TYPE: Journal; General Review
LANGUAGE: English

AB A review with 46 refs. Some believe that an abnormal immunoregulatory response based on environmental damage to T cells is fundamental to the prodn. of symptoms in patients with alleged multiple chem. sensitivity and/or environmental illness. According to this theory stimulation of T cells or T cell phenotypic subsets by environmental chems. results in release of cytokines that can effect appropriate target cells of multiple organ systems, resulting in a wide range of symptoms. This concept is reinforced by frequent media reporting of pollution incidents and environmental disasters plus continued isolated reports of immunol. abnormalities in patients with various forms of alleged environmental illness, multiple chem. sensitivities, or other related syndromes. These include reports of slight perturbations in quantity and function of Igs, complement and its components, B cells, natural killer cells, T cells, phenotypic T cell subsets, and helper suppressor T cell ratios. There are also reports of increased or decreased interleukin levels including IL-1 and IL-2 or their receptors (IL-2R) in these patients. Such assays are not infrequently performed even though there is no evidence for their **diagnostic** efficacy in these alleged conditions. It is reasonable, however, to anticipate that with the wide development of assays for many of the interleukins and their receptors, these assays may become important in the future **diagnosis** of many autoimmune, allergic, neoplastic, and infectious diseases. At this time, however, the induction of environmental illness or multiple chem. sensitivity by exposure to trace levels of environmental immunotoxins is unproven and remains a matter of speculation. The reproducibility of immunol. test abnormalities reported under these conditions has not been documented, and the data have often not been analyzed statistically. Appropriate controls also have not usually been employed, nor have control values been provided in many cases. Consideration must also be given to an understanding of biol. variability and diurnal variations in lymphoid cell nos. in interpreting cellular immunol. profiles. In addn., many other conditions can effect immunol. tests, such as medications, psychol. factors, cigarette smoking, and the presence of concurrent disease, including minor viral infections. All of these variables should be appreciated in test interpretation. Attempts are made to outline the various quant. and functional tests used to assess the immune system, with emphasis on biomarker tests to detect possible immune system damage.

L7 ANSWER 9 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1996:674600 CAPLUS
DOCUMENT NUMBER: 125:321888

TITLE: New developments in particle-based **immunoassays**: introduction
AUTHOR(S): Bangs, Leigh B.
CORPORATE SOURCE: Bangs Lab. Inc., Carmel, IN, 46032-2823, USA
SOURCE: Pure Appl. Chem. (1996), 68(10), 1873-1879
CODEN: PACHAS; ISSN: 0033-4545
DOCUMENT TYPE: Journal; General Review
LANGUAGE: English

AB A review with 34 refs. There have been many innovations in **diagnostics** since white latex particles or microspheres were first used in medical **diagnostic** applications as "latex" agglutination tests (LAT) in the late 1950's. These innovations include colored particles permitting multivalent (or simultaneous) analyses, and special devices for simplifying test execution and result interpretation. Dyed agglutinated particles caught on filters form the basis of another class of tests. Sensitive particle-enhanced turbidimetric assays are in common use and are read with **clin. chem.** analyzers ia spectrophotometric or nephelometric methods. Particle capture ELISA tests and assays are in common use. The popular new strip tests for pregnancy, ovulation, drugs of abuse in urine, and many other tests all use dyed microspheres (and some use two types of microspheres). Solid phase assays and tests use particles as a solid phase for pos. or neg. capture of a wide variety of analytes. Solid-liq. sepns. can be made by centrifugal d. sepn., or filtration, or via magnetic sepn. of superparamagnetic particles. Single microsphere (and perhaps single mol. sensitivity) assays are now possible in flow cytometers.

L7 ANSWER 10 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1996:276407 CAPLUS
DOCUMENT NUMBER: 124:334897
TITLE: Instrumentation methods and automation in nucleic acid assays
AUTHOR(S): Khalil, Omar S.
CORPORATE SOURCE: Probe Diagnostics Program, Abbott Laboratories, Abbott Park, IL, 60064, USA
SOURCE: Cancer Mol. Biol. (1995), 2(6), 669-81
CODEN: ICMBEZ
DOCUMENT TYPE: Journal; General Review
LANGUAGE: English

AB A review and discussion with 86 refs. Nucleic acid assays have the potential to drastically change the clin. **diagnostics** field as assays for cancer markers and genetic predisposition to diseases are developed. In addn., these assays are gradually replacing culture assays for agents of infectious disease because of the increased sensitivity and shortened turnaround time. Most of the current com. systems are directed towards infections disease testing and have very low system throughput for sample prepn.,

amplification, and detection. Whereas **clin. chem**
. and **immunoassays** have been transformed by the
introduction of automation, nucleic acid-based assays have so far
been little affected. There are several reasons for the lack of
automation in nucleic acid **diagnostics** compared to
**clin. chem.** or **immunoassays**:. (I) The
embryonic nature of the field. (Ii) The lack of a universally
accepted technol. ready to be adapted to lab. automation. (Ii) The
variable nature of specimens used in nucleic acid assays. (I.v.)
The sensitivity of nucleic acid-based assays renders them extremely
sensitive to contamination. (V) Some of the practices used in early
research amplification reaction assays such as the addn. of wax
beads for hot start reactions, addn. of oil overlay in amplification
vials and addn. of silicon oil in thermal cycle wells were not
amenable for automation. As the mol. biol. techniques become
established and the precise of the assays moves away from
unnecessary complicated steps, automation efforts can decrease
result's turnaround time and increase system throughput while
minimizing contamination. In this review the different steps in
nucleic acid assays and the impact of automation on these steps is
discussed. Com. available amplification assay systems are described
and the future of assay automation considered. Two recent books
reviewed the mol. biol. and protocol aspects of nucleic acid probe
assays. This review emphasizes the instrumentation aspects of these
and a micro-titrn. plate reader.

L7 ANSWER 11 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1995:892818 CAPLUS
DOCUMENT NUMBER: 124:49955
TITLE: Effects of standardization with the new international reference preparation for proteins in human serum on method comparability and reference values
AUTHOR(S): Hafner, G.; Endler, T.; Oppitz, M.; Merten, U. P.; Toepfer, G.; Dubois, H.; Hallstein, A.; Hilger, B.; Domke, I.
CORPORATE SOURCE: Inst. Klin. Chem., Johannes-Gutenberg Univ., Mainz, Germany
SOURCE: Klin. Labor (1995), 41(10), 743-8
CODEN: KLLAEA; ISSN: 0941-2131
DOCUMENT TYPE: Journal
LANGUAGE: English
AB Eight **immunoassays** for detg. human serum proteins,
Tina-quant C3, C4, CRP, IgA, IgG, IgM, transferrin, and
bromocresol-green method albumin, were standardized with CRM 470,
the new international ref. prepn. for human serum proteins prepd. by
the IFCC. Conversion factors from the current to the IFCC
standardization are shown. The comparability between different
methods (immunoturbidimetry/bromocresol-green method, fixed-time

nephelometry, rate nephelometry, radial immunodiffusion) for albumin, C4, IgA, and IgM is improved by using CRM 470. No relevant effects are obsd. for C3, CRP, IgG, and transferrin. A ref. range study was performed in 1 lab. The ref. values have contributed to the new consensus values of the German Society of Lab. Medicine, the German Society of **Clin. Chem.**, and the Assocn. of the German **Diagnostic** Industry. These new ref. ranges are recommended for various immunochem. methods.

L7 ANSWER 12 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1995:780139 CAPLUS
DOCUMENT NUMBER: 124:4258
TITLE: Adaptation of the **diagnostic** strategy of urine protein differentiation to the Hitachi 911 analyzer
AUTHOR(S): Schmidt, D.; Hofmann, W.; Guder, W. G.
CORPORATE SOURCE: Inst. Klin. Chem., Staedt. Krankenhaus Muenchen-Bogenhausen, Munich, Germany
SOURCE: Laboratoriumsmedizin (1995), 19(4), 153-61
CODEN: LABOD3; ISSN: 0342-3026
DOCUMENT TYPE: Journal
LANGUAGE: German
AB Quantification of defined urine proteins has become the optimal strategy for excluding and differentiating various causes of proteinuria and hematuria. The following quant. methods were adapted to the Hitachi 911 analyzer: total protein with turbidimetry (TCA/HCl), albumin, IgG, .alpha.1-microglobulin, .alpha.2-macroglobulin with immunoturbidimetry, N-acetyl-.beta.-D-glucosaminidase (kinetic), and creatinine with the kinetic Jaffe procedure. The wide range of concns. occurring in normal and pathol. urines was covered by choosing 2 different method variations, a sensitive variation and a less sensitive one for each of the procedures for protein, albumin, IgG, .alpha.1-microglobulin, and .alpha.2-macroglobulin in combination with the analyzer-specific diln. strategy. Inter- and intra-assay precisions of these methods were in the range of routine procedures for **clin. chem.** (<5% CV), and carryover of sample was prevented by washing steps, thus making it possible to analyze urines and plasmas/sera in random sequence. Bidirectional coupling of the analyzer to the inhouse computer system allowed optional method selection depending on the test strip result. Anal. results were transferred to a personal computer expert system for medical validation and interpretation.

L7 ANSWER 13 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1995:594625 CAPLUS
DOCUMENT NUMBER: 123:78900
TITLE: Urinary concentration of a specific peptide of type I collagen of bone (CrossLaps): correlation

to hydroxyproline
AUTHOR(S): Silsand, T.; Reine, A.; Dugal, S.; Lunde, T.; Smedsrud, B.; Seeberg, T.
CORPORATE SOURCE: Department of Clinical Chemistry, Telemark Central Hospital, Porsgrunn, 3900, Norway
SOURCE: Scand. J. Clin. Lab. Invest. (1995), 55(2), 187-92
CODEN: SJCLAY; ISSN: 0036-5513
DOCUMENT TYPE: Journal
LANGUAGE: English
AB Urinary bone resorption markers, CrossLaps and hydroxyproline are compared in a non-selected group of 93 women. The correlation between CrossLaps and hydroxyproline is satisfactory. The r value is 0.79. Furthermore, it is investigated whether CrossLaps can substitute for hydroxyproline in the estn. of bone loss, using a model based on the combination of several **biochem.** **markers**. The results indicate that the two systems reflect related or parallel events, and show that CrossLaps is suitable for use in a normal **clin. chem.** lab.

L7 ANSWER 14 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1995:296567 CAPLUS
DOCUMENT NUMBER: 122:74103
TITLE: Sensitivity and specificity of cocaine metabolite screening in view of the analytical performance of a fluorescence polarization **immunoassay**
AUTHOR(S): Haenseler, E.; Keller, H.
CORPORATE SOURCE: Inst. Clinical Chem., Univ. Hospital Zuerich, Switzerland, Switz.
SOURCE: Eur. J. Clin. Chem. Clin. Biochem. (1994), 32(11), 865-71
CODEN: EJCBEO; ISSN: 0939-4974
DOCUMENT TYPE: Journal
LANGUAGE: English
AB A hundred urine samples from people suspected of cocaine abuse and 50 urine samples from patients unlikely to have consumed cocaine were analyzed in triplicate with a com. available fluorescence polarization **immunoassay**. From this data we assessed the anal. variance of the assay using the computer program of Sadler & Smith (**Clin. Chem.** 36 (1990), 1346-1350). Using the functions provided, we calcd. the limit of detection (LD) and the lower limit of quantification (LLQ) as well as the so-called power of definition (PD) using a recently published method (Gautschi et al., this journal 31 (1993), 433-440). This procedure is math. well defined, uses no artificial stds. or calibrators and is in compliance with IFCC recommendations. A clearly defined assessment of the **diagnostic** performance of an assay is of utmost importance for the discussion of adequate decision levels. The

influence of different decision levels was demonstrated by assessing the **diagnostic** performance of the FPIA assay for benzoylecgonine by calcg. the predictive values of a neg. and pos. test result for four different decision limits (12, 40, 150, recommended by DoD and 300 .mu.g/L, recommended by NIDA). The resp. predictive values of the neg. results were 0.931, 0.864, 0.704 and 0.661. The predictive value of a pos. test result was uniformly 1.0 for all four cut-offs. These results are critically discussed with respect to the anal. performance of the assay, the socio-economic and legal consequences of the screening procedure.

L7 ANSWER 15 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1994:602696 CAPLUS
DOCUMENT NUMBER: 121:202696
TITLE: Determination of rheumatoid factors by an **immunoturbidimetric assay** on Boehringer Mannheim/Hitachi analysis systems
AUTHOR(S): Borque De Larrea, Luis; Barozzi, Daniela; Ferrari, Luigi; Gamp, Reiner; Ulbricht, Gisela; Van Oers, Rene J. M.; Leerkes, Ben; Szymanowicz, Anton; Zaman, Zahur; et al.
CORPORATE SOURCE: Lab. Bioquim., Hosp. San Millan, Logrono, E-26004, Spain
SOURCE: Klin. Labor (1994), 40(5), 445-53
CODEN: KLLAEA
DOCUMENT TYPE: Journal
LANGUAGE: English

AB A turbidimetric assay for detn. of rheumatoid factors (RF) has been evaluated in 7 labs. on different Boehringer Mannheim/Hitachi anal. systems. The Tina-quant RF test is based upon the reactions between IgM-anti-IgG (RF) and latex-coated heat-aggregated IgG which result in agglutination. The linear relation between absorbance and concn. permits a linear calibration. The assay enables the quantification of RF activities below 7.5 IU/mL and is linear up to 120 IU/mL. Within-run coeffs. of variation range from 0.6 to 8.1% and between-day coeffs. of variation from 1.6 to 9.8%. A satisfactory recovery from different control sera is obtained. RF activities detd. within an interlab. survey on different anal. systems agree well. The differences obsd. between all methods employed demonstrate the state of the art situation for the comparability of RF assays. An upper limit of the ref. interval of 14 IU/mL RF is established from a ref. range study. This value corresponds to a **diagnostic** sensitivity of 79%, a specificity of 93%, and an efficiency of 72%. The **immunoturbidimetric assay** enables the convenient detn. of RF on routine **clin. chem.** analyzers and yields results with a high **diagnostic** efficiency.

L7 ANSWER 16 OF 29 CAPLUS COPYRIGHT 1999 ACS

ACCESSION NUMBER: 1994:476771 CAPLUS
DOCUMENT NUMBER: 121:76771
TITLE: Evaluation of an **immunoradiometric assay** for bone alkaline phosphatase mass concentration in human sera
AUTHOR(S): Withold, W.; Rick, W.
CORPORATE SOURCE: Inst. Klin. Chem. Laboratoriumsdiagn., Med. Einrichtunger, Heinrich-Heine-Univ., Duesseldorf, Germany
SOURCE: Eur. J. Clin. Chem. Clin. Biochem. (1994), 32(2), 91-5
CODEN: EJCBEO; ISSN: 0939-4974
DOCUMENT TYPE: Journal
LANGUAGE: English

AB The performance characteristics of an RIA for bone alk. phosphatase mass concn. in human sera are reported. Within-run imprecision (n = 20) was 12.1% (.hivin.x = 7.8 .mu.g/L) and 3.6% (.hivin.x = 22.8 .mu.g/L); between-day imprecision (n = 8) was 10.1% (.hivin.x = 20.3 .mu.g/L) and 2.8% (.hivin.x = 84.3 .mu.g/L). There was a linear relation between the concns. of the stds. employed and the counts per min up to 120 .mu.g/L. The detection limit was 0.3 .mu.g/L. In 102 apparently healthy persons (51 males and 51 females; range of age: 18-56 yr) the following ref. intervals were established: 3.8-21.3 .mu.g/L (males) and 3.4-15.0 .mu.g/L (females). The authors compared the values obtained using the RIA with those obtained by pptg. bone alk. phosphatase with wheat-germ lectin (alk. phosphatase activity concn. was detd. at 25.degree.by the optimized std. method according to the Recommendations of the German Society of **Clin. Chem.**). For the ref. individuals, the relation between the results of the 2 methods is given by the following regression equation: bone alk. phosphatase activity concn. [U/L] = 14.81 + 3.28 .times. bone alk. phosphatase mass concn. [.mu.g/L] (r = +0.783). In 89 sera from 32 patients before and after renal transplantation (range of bone alk. phosphatase mass concn.: 2-39 .mu.g/L) comparison between the 2 methods yielded a linear correlation coeff. of r = 0.886. Of 20 sera taken from patients suffering from various hepatobiliary diseases (range of total alk. phosphatase activity concn.: 217-3270 U/L) 18 (90%) showed a bone alk. phosphatase mass concn. above the upper ref. limit (range of bone alk. phosphatase mass concn.: 16-206 .mu.g/L). This was probably due to a cross-reactivity of the antibodies employed for the RIA of bone alk. phosphatase with liver alk. phosphatase in plasma. It was concluded that an increased release of liver alk. phosphatase into serum leads to falsely high values for bone alk. phosphatase mass concn., severely limiting the **diagnostic** validity of the test in such cases.

L7 ANSWER 17 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1994:72649 CAPLUS

DOCUMENT NUMBER: 120:72649
TITLE: HPTLC as a reference method in **clinical chemistry**: online coupling with spectroscopic methods
AUTHOR(S): Wagner, Juergen; Jork, Hellmut; Koglin, Eckhard
CORPORATE SOURCE: Dep. Pharm. Biol. Chem., Univ. Saarland, Saarbruecken, 66 041, Germany
SOURCE: J. Planar Chromatogr.--Mod. TLC (1993), 6(6), 446-51
CODEN: JPCTE5; ISSN: 0933-4173
DOCUMENT TYPE: Journal
LANGUAGE: English
AB **Immunoassay** methods play an important role in the routine detn. of active substances in body fluids. Since cross reactions are frequently obsd., reliable ref. methods are required to check the results. Chromatog. methods are suited for this purpose. By exploiting the high sepn. performance of modern thin layer chromatog. in conjunction with selective identification techniques it is possible to sep. theophylline without difficulty from its positional isomers and from other xanthine derivs. Identification can be performed using online spectrophotometric methods (UV/VIS, FTIR, and Raman) or microchem. methods. These increase the reliability of the identification prior to quant. anal. This is of particular importance for unequivocal **diagnosis** as the basis for further clin. therapeutic measures.

L7 ANSWER 18 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1993:250830 CAPLUS
DOCUMENT NUMBER: 118:250830
TITLE: **Clinical chemistry**
AUTHOR(S): Anderson, David J.; Van Lente, Frederick
CORPORATE SOURCE: Dep. Chem., Cleveland State Univ., Cleveland, OH, 44115, USA
SOURCE: Anal. Chem. (1993), 65(12), 364r-84r
CODEN: ANCHAM; ISSN: 0003-2700
DOCUMENT TYPE: Journal; General Review
LANGUAGE: English
AB A review with many refs. covering clin. topics (e.g., cardiovascular disorders, endocrine disorders), bone disorders, etc.) and instrumental topics (e.g., mol. biol. techniques, **immunoassays**, HPLC, etc.).

L7 ANSWER 19 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1993:208843 CAPLUS
DOCUMENT NUMBER: 118:208843
TITLE: Multicenter evaluation of **immunoturbidimetric assays** for apolipoproteins A-I and B
AUTHOR(S): Jarausch, J.; Casals, E.; Gnat, D.; Drexel, H.;

Huchet, F. X.; Patsch, J.; Wieland, H.
CORPORATE SOURCE: Eval. Dep., Boehringer Mannheim GmbH, Mannheim, D-6800/31, Germany
SOURCE: Mol. Biol. Atheroscler., [Ed. Proc. Eur. Atheroscler. Soc. Meet.] (1992), Meeting Date 1991, 397-403. Editor(s): Halpern, Manuel Judice. Libbey: London, UK.
CODEN: 58QDA6
DOCUMENT TYPE: Conference
LANGUAGE: English
AB Two **immunoturbidimetric assays** for apolipoproteins A-I and B were evaluated in five labs. The measurements were performed on BM/Hitachi 704/717 and COBAS Mira **clin. chem.** analyzers. Comparing the method with automated routine assays a reasonable comparability was obtained with apo A-I, whereas larger discrepancies were found with some of the routine procedures for apo B. The results indicate that the new reagents can be successfully integrated into std. lipid **diagnostics** performed on **clin. chem.** analyzers.

L7 ANSWER 20 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1992:51705 CAPLUS
DOCUMENT NUMBER: 116:51705
TITLE: The determination of thyroxine and thyroxine uptake with new homogeneous enzyme **immunoassays** using Boehringer Mannheim/Hitachi analysis systems
AUTHOR(S): Horn, K.; Castineiras, M. J.; Ortola, J.; Kock, R.; Perriard, F. C.; Bittner, S.; Pairet, J. V.; Ers, P.; Boulanger, J.; et al.
CORPORATE SOURCE: Med. Klin. Innenstadt, Univ. Muenchen, Munich, Germany
SOURCE: Eur. J. Clin. Chem. Clin. Biochem. (1991), 29(10), 697-703
CODEN: EJCBEO; ISSN: 0939-4974
DOCUMENT TYPE: Journal
LANGUAGE: English
AB New homogeneous enzyme **immunoassays** for the detn. of thyroxine and thyroxine uptake have been developed. The CEDIA assays are based on the cloned enzyme donor **immunoassay** technol., which involves fragments of .beta.-galactosidase prepd. by genetic engineering. The assays have been adapted for Boehringer Mannheim/Hitachi analyzers. The CEDIA T4/T uptake assays were evaluated in 11 **clin. chem.** labs. on various Boehringer Mannheim/Hitachi anal. systems, using a 2-point calibration. The anal. range of the T4 test was 10-258 nmol/L thyroxine. The T uptake test had a measuring range of 20-50%. Depending on the concn. of the analyte (samples from hypo-, eu- or

hyperthyroid patients), mean coeffs. of variation ranged from 1.8 to 4.8% within-run and from 4.1 to 6.5% between-run for the T4 assay. Even better coeffs. of variation were obtained for the T uptake assay (1.4 to 2.3% within-run, 2.8 to 3.3% between run). The relative inaccuracy of the CEDIA assays with respect to values assigned by other tests was satisfactory in various control sera. The T4 assay was compared with 1 RIA, 1 enzyme **immunoassay**, and 1 fluorescence polarization **immunoassay**. Slopes ranging from 0.9 to 1.1 and intercepts ranging from -10 to +10 nmol/L thyroxine were obtained with 2 exceptions. The results of the T uptake test correlated reasonably with those of other thyroxine-binding methods. No interference was obsd. with icteric and lipemic sera. Hb up to 4 g/L had no significant influence. Results of the CEDIA T uptake test are mainly used for calcn. of the free thyroxine index, in which the thyroxine value is cor. for variations of thyroxine-binding protein concns. The free thyroxine index is related to the concn. of free T4 detd. by enzyme **immunoassay**. In conclusion, the CEDIA T4/T uptake assays are convenient and reliable methods which offer an alternative in thyroid **diagnostics** in combination with routine **clin. chem.** on Boehringer Mannheim/Hitachi analyzers.

L7 ANSWER 21 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1990:607149 CAPLUS
DOCUMENT NUMBER: 113:207149
TITLE: Clinical evaluation of an automated chemical inhibition assay for lactate dehydrogenase isoenzyme 1
AUTHOR(S): Onigbinde, Toafig A.; Wu, Alan H. B.; Johnson, Myrtle; Wu, Yih Shiong; Collinsworth, William L.; Simmons, Mark J.
CORPORATE SOURCE: Med. Sch., Univ. Texas, Houston, TX, 77225, USA
SOURCE: Clin. Chem. (Winston-Salem, N. C.) (1990), 36(10), 1819-22
CODEN: CLCHAU; ISSN: 0009-9147
DOCUMENT TYPE: Journal
LANGUAGE: English
AB An automated assay for lactate dehydrogenase (LD; EC 1.1.1.27) isoenzymes, supplied by Boehringer Mannheim **Diagnostics** (BMD) and based on selective chem. inhibition of non-LD-1 isoenzymes by guanidine thiocyanate was evaluated. The results were compared with the Roche Isomune LD-1 method. The Hitachi 717 analyzer was used to measure enzyme activity for both procedures in 299 serum samples. One hundred specimens were also analyzed by the Helena rapid electrophoresis (REP) method. The limit of linearity of the BMD method was detd. to be .apprx.1200 U LD-1/L. The anal. correlation of BMD (y) with Isomune (x) yielded y - 1.0x + 0.5 U/L, r = 0.997, Sy/x = 16.9 (range, 20-1397 U/L). The regression

equation for BMD vs. REP was y = 1.1x + 7.2% (r = 0.800, Sy/x = 7.4, range, 14-83%). Av. values for within-run precision for low (38 U/L), medium (180 U/L), and high (865 U/L) controls were 4.1, 1.0, and 0.5%, resp. (16 trials of 6 each). The av. values fo run-to-run precision were 4.1, 1.7, and 1.1%, resp., for these controls (n = 16). Receiver-operating characteristic curves were used to det. optimum decision limits. Using an LD-1 cutoff of 40% of total LD, a clin. sensitivity of 97-100% and a specificity of 95% when blood was collected during the optimum interval, 24-48 h after the onset of chest pain were obtained. It was concluded that the BMD LD-1 assay is equiv. to the **immunochem**. and electrophoretic **assays** for measuring the LD-1 isoenzyme.

L7 ANSWER 22 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1985:556595 CAPLUS
DOCUMENT NUMBER: 103:156595
TITLE: Fluorescence **immunoassay** in clinical-chemical **diagnosis**
AUTHOR(S): Hubl, W.; Hofmann, F.; Meissner, D.
CORPORATE SOURCE: Inst. Klin. Chem. Laboratoriumsdiagnostik, Bezirkskrankenhauses Dresden-Friedrichstadt, Dresden, Ger. Dem. Rep.
SOURCE: Z. Med. Laboratoriumsdiagn. (1985), 26(5), 243-53
CODEN: ZMLADB; ISSN: 0323-5637
DOCUMENT TYPE: Journal
LANGUAGE: German
AB Principles and types of fluorescence **immunoassays** are described, as well as different fluorescent markers. Examples of application included cortisol detn. in secondary kidney disorders, aldosterone detn. in Conn's syndrome and Addison's disease, and 17-hydroxyprogesterone detn. in adrenogenital syndrome before and after corticoid therapy. The title **immunoassay** is compared to EIA and RIA.

L7 ANSWER 23 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1985:145492 CAPLUS
DOCUMENT NUMBER: 102:145492
TITLE: **Clinical chemistry**
AUTHOR(S): Stinshoff, K. E.; Freytag, J. W.; Laska, P. F.; Gill-Pazaris, Lori
CORPORATE SOURCE: Biomed. Prod. Dep., E. I. du Pont de Nemours and Co., Wilmington, DE, 19898, USA
SOURCE: Anal. Chem. (1985), 57(5), 114R-130R
CODEN: ANCHAM; ISSN: 0003-2700
DOCUMENT TYPE: Journal; General Review
LANGUAGE: English
AB A review with 478 refs. covering instrumentation, computerized data management, **immunoassays** and the use of monoclonal

antibodies, analytes of clin. interest in the **diagnosis** of, e.g., tumors, infectious and endocrine diseases, and atherosclerosis, and detn. of biol. response modifiers.

L7 ANSWER 24 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1985:74517 CAPLUS
DOCUMENT NUMBER: 102:74517
TITLE: Immunological procedures in clinical enzyme **diagnostics**
AUTHOR(S): Bohner, Juergen; Stein, W.
CORPORATE SOURCE: Abt. Inn. Med. IV, Universitaetsklin. Tuebingen, Tuebingen, D-7400, Fed. Rep. Ger.
SOURCE: J. Clin. Chem. Clin. Biochem. (1984), 22(12), 943-52
CODEN: JCCBDT; ISSN: 0340-076X
DOCUMENT TYPE: Journal; General Review
LANGUAGE: English
AB A review with 92 refs. The general potentialities of the immunol. detn. of enzymes are presented by using creatine kinases and phosphatases as examples to describe the most important variants of the **immunoassay** for **clin. chem.** enzyme **diagnositics**. The principle of each test and the resp. possibilities of interference are described. The anal. efficiency and applicabilities of these **immunoassays** are assessed critically.

L7 ANSWER 25 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1985:20083 CAPLUS
DOCUMENT NUMBER: 102:20083
TITLE: "PMN-elastase **assay**": enzyme **immunoassay** for human polymorphonuclear elastase complexed with .alpha.1-proteinase inhibitor
AUTHOR(S): Neumann, S.; Gunzer, G.; Hennrich, N.; Lang, H.
CORPORATE SOURCE: Biochem. Res. Inst., E. Merck, Darmstadt, D-6100, Fed. Rep. Ger.
SOURCE: J. Clin. Chem. Clin. Biochem. (1984), 22(10), 693-7
CODEN: JCCBDT; ISSN: 0340-076X
DOCUMENT TYPE: Journal
LANGUAGE: English
AB A solid-phase, enzyme-linked **immunoassay** is described for the quant. detn. of the complex of human granulocyte elastase (EC 3.4.21.37) with .alpha.1-proteinase inhibitor. The assay employs antibody-coated test tubes and it is suitable for routine use in **clin. chem.** labs. Data for sample stability and test characteristics are given. A ref. range of 20-180 .mu.g elastase/L plasma was detd. The **diagnostic** significance of polymorphonuclear (PMN) leukocyte elastase levels in plasma in

inflammatory diseases is discussed.

L7 ANSWER 26 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1981:528488 CAPLUS
DOCUMENT NUMBER: 95:128488
TITLE: Medical **diagnostic** reagents
AUTHOR(S): Spiegel, H. E.
CORPORATE SOURCE: Hoffmann-La Roche Inc., Freeport, TX, USA
SOURCE: Kirk-Othmer Encycl. Chem. Technol., 3rd Ed. (1981), Volume 15, 74-92. Editor(s): Grayson, Martin; Eckroth, David. Wiley: New York, N. Y. CODEN: 37ASAA
DOCUMENT TYPE: Conference; General Review
LANGUAGE: English
AB A review with refs. on medical **diagnostic** reagents used in the **clin. chem.** lab. Colorimetric, chromatog., immunoradioassay, and enzyme **immunoassay** techniques are described. Theor. and practical aspects of a reagent kit used are discussed along with basic elements of interpretation of results.

L7 ANSWER 27 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1978:185797 CAPLUS
DOCUMENT NUMBER: 88:185797
TITLE: Method and apparatus for performing chemical and clinical analyses
INVENTOR(S): Conti, Filippo
PATENT ASSIGNEE(S): CIROT Compagnia d'Ingegneria per la Realizzazione di Opere Tecniche S.p.A., Italy
SOURCE: Ger. Offen., 16 pp. CODEN: GWXXBX
DOCUMENT TYPE: Patent
LANGUAGE: German
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

| PATENT NO. | KIND | DATE | APPLICATION NO. | DATE |
|---|---|---|---|---|
| DE 2636312 | A1 | 19780216 | DE 76-2636312 | 19760812 |

AB A method and app. for **chem.** and **clin.** anal. are described in which the substance to be analyzed is brought into contact with a specific reagent, an enthalpy change occurs due to the contact, and the value of the enthalpy change is converted into a signal and measured. The app. contains a thermostated 2-compartment chamber into which 2 cylinders are placed and connected by a transverse channel. Thus, cylinders were washed twice, dried in a vacuum and a soln. of anti-A-antiserum was layered .apprx.0.25 mm thick on 1 cylinder, on the 2nd cylinder a layer of anti-B-antiserum was placed, and on a 3rd cylinder anti-AB-antiserum. The cylinders were placed in a vacuum for 1 h so

that the reagents were absorbed on the Al2O3 surface of the cylinders. One mL of blood sample was introduced into the channel and if the sample contains blood group A, it reacts with the cylinder contg. anti-A and a signal is obtained. Similarly, lactate dehydrogenase activity detn. and **immunoassay** of an antigen, gonadotropin, were carried out.

L7 ANSWER 28 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1977:548332 CAPLUS
DOCUMENT NUMBER: 87:148332
TITLE: Method and apparatus for carrying out chemical and clinical analyses
PATENT ASSIGNEE(S): CIROT Compagnia d'Ingegneria per la Realizzazione di Opere Techniche S.p.A., Italy
SOURCE: Fr. Demande, 12 pp.
CODEN: FRXXBL
DOCUMENT TYPE: Patent
LANGUAGE: French
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

| PATENT NO. | KIND | DATE | APPLICATION NO. | DATE |
|---|---|---|---|---|
| FR 2319903 | A1 | 19770225 | FR 76-23612 | 19760802 |
| FR 2319903 | B3 | 19790504 | | |
| PRIORITY APPLN. INFO.: | | | IT 75-50787 | 19750801 |

AB The title method is characterized by reacting a substance to be studied (antigen, enzyme, etc.) with a specific reagent (antibody, substrate, etc.) to produce a change in enthalpy that is detected and recorded by the assocd. app. The app. comprises a thermostated chamber, to receive the substance to be studied, in which is inserted a hollow cylinder carrying on its external surface the specific reagent and in which is placed a highly sensitive thermoelec. probe that forms part of an elec. circuit comprised of a source of elec. current, a means to transform the signal transmitted by the probe, and a means to amplify the signal. An example is given for the detn. of gonadotropin, (antigen) in urine by means of a specific antibody in which the antibody is adsorbed to an anodized Al support, and the support is placed in the thermostated cell. After urine is injected into the cells the appearance of a peak on a recorder indicates the presence of gonadotropin in urine, confirming the **diagnosis** of pregnancy.

L7 ANSWER 29 OF 29 CAPLUS COPYRIGHT 1999 ACS
ACCESSION NUMBER: 1973:107870 CAPLUS
DOCUMENT NUMBER: 78:107870
TITLE: Significance of the LP-X [Lipoprotein-X] test in differential **diagnosis** of jaundice
AUTHOR(S): Seidel, D.; Gretz, H.; Ruppert, Claudia

CORPORATE SOURCE: Med. Sch., Univ. Heidelberg, Heidelberg, Ger.
SOURCE: Clin. Chem. (1973), 19(1), 86-91
CODEN: CLCHAU
DOCUMENT TYPE: Journal
LANGUAGE: English
AB The characteristic increase in plasma lipoproteins in patients with obstructive jaundice is the result of the presence of a low-d. lipoprotein (relative d. 1.006-1.063 g/ml) of abnormal compn. and properties. This abnormal lipoprotein was designated LP-X. The development of a simple immunol. test system for detg. LP-X provides the basis for a new **clin. chem.** test used in the **diagnosis** of jaundice. In this study, 2680 LP-X detns. were performed on 1481 subjects: 1309 patients with or without liver disease, and 172 healthy volunteers. Statistical anal. of this series (4-fold .chi.2 test) revealed a power of 0.99 and a specifity of 0.98 to demonstrate or exclude cholestasis. In this regard, the new test is superior to other blood-chem. assessments. It was never pos. in patients without liver disease. However, the LP-X test alone is not adequate to distinguish between intrahepatic cholestasis and extrahepatic biliary obstruction.

=> d his l8-; d 1-38 ibib abs

(FILE 'MEDLINE, BIOSIS, EMBASE, LIFESCI, BIOTECHDS, WPIDS, CONFSCI, SCISEARCH, JICST-EPLUS, PROMT' ENTERED AT 14:51:21 ON 04 MAY 1999)
L8 2202 S L7
L9 7 S L8 AND PROCESSOR
L10 10 S L8 AND ALGORITH?
L11 26 S L8 AND NETWORK?
L12 38 S L9 OR L10 OR L11
L13 38 DUP REM L12 (0 DUPLICATES REMOVED)

L13 ANSWER 1 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 1999:109663 PROMT
TITLE: IGEN and USDA Announce Agreement on Development of E.coli 0157:H7 And Other Food and Beverage Tests.
SOURCE: PR Newswire, (22 Feb 1999) pp. 9060.
PUBLISHER: PR Newswire Association, Inc.
DOCUMENT TYPE: Newsletter
LANGUAGE: English
WORD COUNT: 541
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*
AB Initial Focus on Commercialization of E.coli 0157:H7
THIS IS THE FULL TEXT: COPYRIGHT 1999 PR Newswire Association, Inc.

L13 ANSWER 2 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 1999:60237 PROMT

TITLE: IGEN Announces Additional Instrument Sales to USDA for E.coli Test Analysis.
SOURCE: PR Newswire, (2 Feb 1999) pp. 6032.
PUBLISHER: PR Newswire Association, Inc.
DOCUMENT TYPE: Newsletter
LANGUAGE: English
WORD COUNT: 456
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB GAITHERSBURG, Md., Feb. 2 /PRNewswire/ -- IGEN International, Inc. (Nasdaq: IGEN) announced today that the USDA acquired four additional ORIGEN Detection Systems to be utilized in field laboratories for analysis of an ORIGEN-based E.coli 0157:H7 test for meat samples. This E.coli test was developed by the Agricultural Research Service (ARS) of the USDA and is based on IGEN's proprietary ORIGEN technology.



L13 ANSWER 3 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 1999:159863 PROMT
TITLE: Dade Behring's Next Act.
AUTHOR(S): Duller, Wendy
SOURCE: In Vivo, The Business & Medicine Report, (Feb 1999) Vol. 17, No. 2, pp. 9(1).
ISSN: 0733-1398.
PUBLISHER: Windhover Information, Inc.
DOCUMENT TYPE: Newsletter
LANGUAGE: English
WORD COUNT: 6295
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB Dade Behring's owners have spent years building up their investment in **diagnostics**. Are they ready to get out?



L13 ANSWER 4 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 1999:17199 PROMT
TITLE: Disease management, information technology are Medica highlights.
SOURCE: The BBI Newsletter, (1 Jan 1999) pp. NA.
ISSN: 1049-4316.
LANGUAGE: English
WORD COUNT: 5533
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB By MICHAEL SIMONSEN DUSSELDORF, Germany - The European medical device and **diagnostics** market, the second-largest worldwide next to the U.S., continues to attract a high level of investment and innovative new products in spite of the uncertain-ties surrounding health care policy trends in the region.

The gigantic Medica 98 exhibition, held here in November, provided a window on the changing Medical market in Europe, as well as a forum for the introduction of a wide range of new products spanning the areas of medical information technology; patient moni-toring; laboratory and alternate-site in vitro **diagnostics**, including self-testing; and computer-assisted surgery.

Statistics on the companies exhibiting at Medica indicate the continued Strong interest in the European market and the medical products market overall, as well as the geographic diversity of the industry. More than 2,650 companies from 54 countries exhibited at the meeting, an increase over the 1997 figure and up sub-stantially from about 2,100 exhibitors from 46 countries in 1996. Exhibitors from Germany accounted for the largest contingent at 1,349, followed by the U.S. with 259, the United Kingdom with 164 and Italy with 148. However, a number of other countries were well-represented, including France (104), Finland (54), Israel (53), the Netherlands (52), Spain (43), Belgium (37), Switzerland (34), Sweden (33), Tai-wan (32), Canada (30) and South Korea (27). Exhibitors also attended from Paraguay, Venezuela, Thailand, Puerto Rico, Australia, Brazil and China.

The European market is entering a key transition as the process of European unification begins to be implemented. The euro became a legal currency on Jan. 1, although euro notes and coins will not become available until Jan. 1, 2002. The economic integration fostered by the introduction of a common currency will augment trends that already have emerged in the medical device and **diagnos**-tics market. These trends include reduction in differentials in selling price between countries, with prices probably gravitating toward the lowest prevailing level; implementation of common regulations governing product registration and labeling; and opening of many country markets to increased competition.



L13 ANSWER 5 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 1999:19855 PROMT
TITLE: IGEN and John Wayne Cancer Institute Announce Important New Findings for the Early Detection of Cancer; Prospects for Wide Use in Cancer Disease Management.
SOURCE: PR Newswire, (12 Jan 1999) pp. 2272.
LANGUAGE: English
WORD COUNT: 977
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB GAITHERSBURG, Md., Jan. 12 /PRNewswire/ -- IGEN International, Inc. (Nasdaq: IGEN) and John Wayne Cancer Institute announced that Dr. Dave Hoon of the Institute, has developed a novel **diagnostic** test for various cancers based on IGEN's

proprietary ORIGEN technology. Dr. Hoon developed a simple and ultra-sensitive blood test for early detection of micrometastases in cancer patients, which can aid physicians in deciding the most appropriate treatment for their patients. Micrometastases, consisting of small numbers of tumor cells colonizing at sites in the body distant from the original tumor, are not ordinarily detectable by existing methodologies. The ORIGEN-based method can be commercialized for use in clinical research, drug development efforts of pharmaceutical companies and, if FDA approved, for use in clinical settings including physicians' offices and oncologists providing care to cancer patients. IGEN is also expanding this collaboration with Dr. Hoon and has obtained an option to exclusively license any novel tests developed by him.

Dr. Hoon discovered that cancer cells can be detected in blood using molecular (DNA) probes. By coupling this discovery with ORIGEN technology he demonstrated a test for cancers that is significantly more sensitive, reproducible, faster, simpler and less expensive than other standard known techniques. "Detection of cancer using sensitive molecular approaches at early stages of cancer progression can improve **diagnosis** and prognosis of patients. This will allow rational approaches for intervention of treatment at early stages of disease progression, which may cure and ultimately improve survival. The test provides **diagnosis** of cancer and examines expression of specific "signature cancer genes" which could help in making decisions on the type of treatment necessary to cure and control disease progression. IGEN ORIGEN technology coupled with specific molecular tumor markers provides a rapid, highly specific and unique approach to detect metastatic disease progression. Current studies are underway to validate the tests' clinical utility and incorporate the tests' findings to improve cancer patient management", said Dr. Hoon.



L13 ANSWER 6 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 1999:254266 PROMT
TITLE: Frost & Sullivan: Hormone Replacement Therapy Revenues Grow With Aging Population.
SOURCE: PR Newswire, (26 Oct 1998) pp. 8875.
PUBLISHER: PR Newswire Association, Inc.
DOCUMENT TYPE: Newsletter
LANGUAGE: English
WORD COUNT: 762
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB MOUNTAIN VIEW, Calif., Oct. 26 /PRNewswire/ -- As the general population, and more specifically the "baby boomer" generation, continues to age, manufacturers of healthcare products have seen the demand for their wares steadily rise. Companies involved in the hormone replacement therapy (HRT) market expect to benefit from this

trend, as they anticipate their revenues to grow along with the aging populace.
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L13 ANSWER 7 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 1999:256857 PROMT
TITLE: The Grand Vision of Roche **Diagnostics**.
AUTHOR(S): Diller, Wendy
SOURCE: In Vivo, The Business & Medicine Report, (Oct 1998) Vol. 16, No. 9, pp. 42(1). ISSN: 0733-1398.
PUBLISHER: Windhover Information, Inc.
DOCUMENT TYPE: Newsletter
LANGUAGE: English
WORD COUNT: 10689
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB Why would a company that gets more than 50% of its revenues from high-margin pharmaceuticals spend billions of dollars on a **diagnostics** business?
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L13 ANSWER 8 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 1999:256424 PROMT
TITLE: Focused Consolidator: bioMerieux.
AUTHOR(S): Diller, Wendy
SOURCE: In Vivo, The Business & Medicine Report, (May 1998) Vol. 16, No. 5, pp. 17(1). ISSN: 0733-1398.
PUBLISHER: Windhover Information, Inc.
DOCUMENT TYPE: Newsletter
LANGUAGE: English
WORD COUNT: 6819
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB As bioMerieux strives to be a leader in infectious diseases, it is confronting lots of competition and rapid consolidation.
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L13 ANSWER 9 OF 38 BIOSIS COPYRIGHT 1999 BIOSIS
ACCESSION NUMBER: 1998:264138 BIOSIS
DOCUMENT NUMBER: PREV199800264138
TITLE: Levels of hepatocyte growth factor/scatter factor (HGF/SF) in seminal plasma of patients with andrological diseases.
AUTHOR(S): Depuydt, Christophe E.; De Potter, Christian R.; Zalata, Adel; Baekelandt, Elsje; Bosmans, Eugene; Comhaire, Frank H. (1)
CORPORATE SOURCE: (1) University Hosp. Ghent, De Pintelaan 185, 9000

Ghent Belgium
SOURCE: Journal of Andrology, (March-April, 1998) Vol. 19, No. 2, pp. 175-182.
ISSN: 0196-3635.
DOCUMENT TYPE: Article
LANGUAGE: English

AB Hepatocyte growth factor/scatter factor (HGF/SF) has all the characteristics of a molecule suitable for functioning in regulatory **networks** of motility, such as the spermatogenic epithelium, where spermatogenic cells must migrate between the cells of Sertoli, and it exerts its effect through binding of its high-affinity receptor (c-met). Considering the findings that c-met receptor is expressed in the human testis and on spermatozoa, and that HGF/SF in seminal plasma consists of pro-HGF/SF, mature alphabeta-HGF/SF, and less active forms of HGF/SF, we investigated the concentration and biological activity of HGF/SF in seminal plasma and their correlation with parameters of spermatogenesis to obtain better insight into mechanisms that may be involved in the pathogenesis of male infertility. We also evaluated the potential value of assessment of hepatocyte growth factor concentration and its bioactivity for the **diagnosis** of certain pathological conditions of male reproduction. We studied the concentration and biological activity of HGF/SF in seminal plasma of normal men and of patients with a range of andrological diseases or conditions by measuring HGF/SF in seminal plasma by enzyme-linked **immunosorbent assay** and by scatter assay using Madin-Darby canine kidney epithelial cells. We identified three sources of HGF/SF in seminal plasma. In samples from vasectomized men (n = 30; 2.01 ng/ml) and in split ejaculate samples (n = 6; 1e fraction 2.75 ng/ml, 2e fraction 1.62 ng/ml), a prostatic origin can be certified. This HGF/SF has low biological activity (133.3 U/ml). In inflammation of the accessory sex glands In = 40), a high amount of HGF/SF (3.04 ng/ml) can be generated by white blood cells and has moderate scatter activity (426.7 U/ml). In normozoospermic samples, there is a lower amount of HGF/SF (1.12 ng/ml), with strong scatter activity (1280.0 U/ml). Finally, the clear difference between the low amount of HGF/SF (1.06 ng/ml) with poor scatter activity (106.6 U/ml) in oligozoospermic samples (n = 28) and the high amount of HGF/SF (3.35 ng/ml) with strong scatter activity (853.3 U/ml) in samples from men with azoospermia of primary testicular failure (n = 18) suggests a mainly testicular origin, with different activity in different pathological conditions.

L13 ANSWER 10 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 1998:494316 PROMT
TITLE: New products signal changing trends in **diagnostics** industry
SOURCE: The BBI Newsletter, (1 Oct 1998) pp. N/A.

ISSN: 1049-4316.
LANGUAGE: English
WORD COUNT: 2509
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB By MICHAEL SIMONSEN, PhD BBI Contributing Writer CHICAGO, Illinois - Companies participating in the clinical **diagnostics** sector are taking different approaches to meeting the changing customer re-quirements wrought by the cost-based turmoil in the health care industry. The bigger players in the in vitro **diagnostics** field are expanding products and tech-nologies in order to offer as broad a line as possible, while small- and mid-sized companies are focusing their product development efforts on those niches offering opportunities for above-average growth. Some of the latter include: * Nucleic acid **diagnostics**, with anticipated growth rates of more than 20% a year over the next more than 20% a year over the next several years. * Whole-blood glucose mon-itoring, expected to grow at 10% to 15% a year. * Various immunochemistry market sectors, including car-diac markers, tumor markers, bone disease markers and infec-tious disease tests. * Point-of-care tests for criti-cal blood parameters. * Tests for use in the home health setting. Testing is rapidly moving out of the traditional hospital setting into clinics, outpatient facilities, and into the patient's home. And testing is rapidly moving away from use of broad panels toward disease-focused testing, nudged along by new regulations requiring that approach. So the volume for classical routine chemistry tests is dropping, while demand for spe-cialized tests that directly impact therapy and triage decisions is rising. The pace of new product introduction in clinical **diagnostics** is probably most rapid in the point-of-care (POC) sector. At this year's American Association for **Clinical Chemistry** (AACC; Washington) meeting, held here in August, Biosite **Diagnostics** (San Diego, Califor-nia) exhibited its new Triage meter providing the capability to perform a cardiac panel including CK-MB, myoglobin, and Troponin I in 15 minutes. This product joins the Stratus CS from Dade Behring (Deerfield, Illinois), which offers the same menu and a turnaround time of as little as 13 minutes for one test and 20 minutes for a three-test panel. The Stratus CS does not perform all three tests using a single device, but rather performs one test per single-use



L13 ANSWER 11 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 1998:476721 PROMT
TITLE: IGEN Announces Agreement With Centers for Disease Control; Agreement to Co-develop Tests for Contaminants in Drinking Water
SOURCE: PR Newswire, (15 Sep 1998) pp. 915NYTU079.
LANGUAGE: English
WORD COUNT: 554

*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB GAITHERSBURG, Md., Sept. 15 /PRNewswire/ -- X IGEN International, Inc. (Nasdaq: IGEN) announced today that it has signed a cooperative research and development agreement (CRADA) with the Centers for Disease Control (CDC) to develop a rapid, reliable, non-microscopic test to detect and quantify Cryptosporidium parvum parasites in water and fecal samples. This test is being formatted for use by drinking water **processors**, bottlers, and testing laboratories. IGEN and the CDC have worked together for several years and have developed a prototype Cryptosporidium test currently being used at the CDC on field water samples.

The CDC said, "This test will be formatted for use by water processing sites and testing laboratories, with real-time data output. Our goal is to optimize the test configuration for automated point of use analysis, and to maximize the test sensitivity. We also propose to develop more efficacious filtration/concentration technologies for water and fecal samples in order to enhance detection of parasites."

Cryptosporidium parasites can cause severe intestinal and renal disease if ingested and possibly death for immunosuppressed people such as the elderly, infants, or AIDS patients. There is currently no fast and simple way to detect Cryptosporidium, with limited testing taking place in highly technical laboratories. The EPA is currently conducting an information collection program to estimate the incidence, and thus the need for mandated testing.

IGEN President Richard J. Massey commented, "Cryptosporidium contamination in water supplies is a worldwide problem. The test developed with the CDC, utilizing IGEN's patented technology, could be the most accurate, sensitive, and fastest test available. Continuing our work with the CDC is a critical part of building the test menus for IGEN's business in food and beverage testing markets." This Cryptosporidium test adds to the hundreds of other applications of IGEN's ORIGEN technology developed for human **diagnostics**, pharmaceutical drug discovery, and environmental testing.



L13 ANSWER 12 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 1998:404401 PROMT
TITLE: Oak Ridge 1998: Big Issues on Small Sizes
SOURCE: Genesis Report-Dx, (1 May 1998) pp. N/A.
ISSN: 1061-2289.
LANGUAGE: English
WORD COUNT: 4458

*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB Have big problems derailed the development of miniaturized **diagnostics**? No, but potentially problematic issues of

sample preparation and sample size will have to be resolved before this technology is commercialized.
The 30th Annual Oak Ridge Conference, which was entitled "Miniaturization of Analytical Systems, Chip-Based Technologies for the Clinical Laboratory," provided a review of efforts to develop miniature **diagnostics** and to overcome the problems confronting that technology. Some of those issues include:
Developing user-friendly sample loading for microchips.
Attaining adequate sensitivity from nanoliter- and picoliter-sized samples.
Manufacturing large quantities of microchips inexpensively.
Some of the companies at the Oak Ridge Conference that presented their research efforts into resolving those issues and producing miniature **diagnostic** chips and devices were:
Affymetrix has developed nanochips with the capability of positioning, metering, linking, and mixing sample and reagent fluids without using sensors.
Caliper Technologies is investigating microchips for DNA analysis, drug screening, **immunoassays**, kinetic **assays**, and complete blood count with the goal of marketing a **diagnostic** chip in 3 to 5 years. Caliper's products use a fluidics system based on electrokinetic forces that control fluid volume, concentration, and movement through channels and reaction chambers.
Nanogen is developing its APEX chips for infectious disease, cancer, and genetic disease **diagnostics**. These microchips can perform multiplexed tests on a single chip.
Boehringer Mannheim and Clinical Micro Systems are exploring microdiagnostic approaches to DNA **diagnostics**.
Metrika is researching a handheld system for quantitative point-of-care testing. Cartridges used in the system incorporate microelectronics, optics, and dry reagents. Up to four tests - which may be any combination of general chemistries and/or **immunoassays** - can be conducted on one sample. The first assay developed with the technology will measure levels in urine of the bone resorption marker NTx.
Beckman Instruments is developing a microscale patterned array capable of performing multianalyte assay technologies. The product is a miniaturized simulation of a 96-well plate. Beckman Instruments has performed four simultaneous **immunoassays** with the same level of sensitivity as a traditional enzyme-linked **immunosorbent assay**.


L13 ANSWER 13 OF 38 BIOSIS COPYRIGHT 1999 BIOSIS
ACCESSION NUMBER: 1997:448668 BIOSIS
DOCUMENT NUMBER: PREV199799747871
TITLE: Advanced multiplexed analysis with the FlowMetrix

system.
AUTHOR(S): Fulton, R. Jerrold (1); McDade, Ralph L.; Smith, Perry L.; Kienker, Laura J.; Kettman, John R., Jr.
CORPORATE SOURCE: (1) Luminex Corp., 1638 Osprey Dr., DeSoto, TX 75115 USA
SOURCE: Clinical Chemistry, (1997) Vol. 43, No. 9, pp. 1749-1756.
ISSN: 0009-9147.
DOCUMENT TYPE: Article
LANGUAGE: English
AB The FlowMetrix System is a multiplexed data acquisition and analysis platform for flow cytometric analysis of microsphere-based assays that performs simultaneous measurement of up to 64 different analytes. The system consists of 64 distinct sets of fluorescent microspheres and a standard benchtop flow cytometer interfaced with a personal computer containing a digital signal processing board and Windows95-based software. Individual sets of microspheres can be modified with reactive components such as antigens, antibodies, or oligonucleotides, and then mixed to form a multiplexed assay set. The digital signal-processing hardware and Windows95-based software provide complete control of the flow cytometer and perform real-time data processing, allowing multiple independent reactions to be analyzed simultaneously. The system has been used to perform qualitative and quantitative **immunoassays** for multiple serum proteins in both capture and competitive inhibition assay formats. The system has also been used to perform DNA sequence analysis by multiplexed competitive hybridization with 16 different sequence-specific oligonucleotide probes.

L13 ANSWER 14 OF 38 BIOSIS COPYRIGHT 1999 BIOSIS
ACCESSION NUMBER: 1997:511460 BIOSIS
DOCUMENT NUMBER: PREV199799810663
TITLE: The utility and cost-effectiveness of D-dimer measurements in the **diagnosis** of deep vein thrombosis.
AUTHOR(S): Crippa, Luciano; D'Angelo, Silvana Vigano; Tomassini, Loredana; Rizzi, Barbara; D'Alessandro, Gabriella; D'Angelo, Armando (1)
CORPORATE SOURCE: (1) Coagulation Service, Istituto Scientifico H S. Raffaele, via Olgettina 60, 20132 Milano Italy
SOURCE: Haematologica, (1997) Vol. 82, No. 4, pp. 446-451.
ISSN: 0390-6078.
DOCUMENT TYPE: General Review
LANGUAGE: English
AB Background and Objective. The potential utility of D-dimer measurements for the **diagnosis** of deep vein thrombosis became evident soon after the development of reliable commercial assays. The purpose of this review is to outline some critical aspects affecting cost-effectiveness of D-dimer measurements in the

**diagnosis** of deep vein thrombosis (DVT). Methods. The authors have been working in this field contributing original papers whose data have been used for this study. In addition, the material analyzed in this article includes papers published in the journals covered by the Science Citation Index' and Medline. Results. D-dimer levels are very sensitive to the process of fibrin formation/dissolution occurring with ongoing thrombosis. However, they may not be highly specific for venous thromboembolism as they are influenced by the presence of comorbid conditions potentially elevating plasma D-dimer (cancer, surgery, infectious diseases). In addition, commercially available ELISA assays, although quantitative and reproducible, cannot be used under emergency conditions because they are time-consuming and suited for batch-processing of plasma samples. Recently, new assays have been introduced which permit fast and quantitative D-dimer estimations in individual patients. We have evaluated the utility of two new rapid assays (LPIA D-dimer, Mitsubishi, and VIDAS D-DIMER, bio-Merieux) in combination with compression realtime-B-mode ultrasonography for the detection of deep vein thrombosis in asymptomatic patients following elective hip replacement and in patients with clinically suspected deep vein thrombosis. In both settings, we identified cut-off values with optimal sensitivity which allow exclusion of deep vein thrombosis in a considerable percentage of patients, with substantial sparing of economic resources. In fact, based on a cost-effectiveness analysis, a **diagnostic algorithm** combining Ddimers measurement and compression ultrasonography would result in cost-savings ranging from 5% to 55% in patients with high or low clinical pretest probability respectively. However, the specificity of D-dimer measurements for deep vein thrombosis was much higher in symptomatic than in asymptomatic patients. Choice of the cut-off value proved to be dependent on the method as well as on the patient populations studied. Conclusions. The cost-effectiveness of D-dimers measurement in the **diagnosis** of asymptomatic DVT remains questionable. Conversely, our data strongly support the utility of D-dimers determinations in the **diagnosis** of symptomatic DVT. in terms of sparing economic resources, the introduction in the clinical laboratory of the rapid quantitative assays would be highly convenient, because they avoid a source of bias in the interpretation of D-dimers results, are easy to perform and do not require dedicated personnel or instrumentation. Prospective management studies validating the utility of D-dimer measurement in the **diagnosis** of deep vein thrombosis are urgently needed.

L13 ANSWER 15 OF 38 BIOSIS COPYRIGHT 1999 BIOSIS
ACCESSION NUMBER: 1997:158731 BIOSIS
DOCUMENT NUMBER: PREV199799457934
TITLE: Field evaluation of rapid HIV serologic tests for screening and confirming HIV-1 infection in Honduras.
AUTHOR(S): Stetler, Harrison C.; Granade, Timothy C. (1); Nunez,

Cesar Antonio; Meza, Rita; Terrell, Stanley; Amador, Lucila; George, J. Richard
CORPORATE SOURCE: (1) Centers Disease Control and Prevention, 1600 Clifton Road D-12, Atlanta, GA 30333 USA
SOURCE: AIDS (London), (1997) Vol. 11, No. 3, pp. 369-375. ISSN: 0269-9370.
DOCUMENT TYPE: Article
LANGUAGE: English
AB Objective: To determine the ability of simple, rapid tests to identify HIV-1 antibody-positive specimens in field settings using the World Health Organization's (WHO) alternative testing strategies. Design: Three-phase evaluation of simple, rapid assays using banked specimens and prospectively collected serum specimens at regional hospitals and rural clinics. Methods: Seven tests (Retrocell, Genie, HIVCHEK, SUDS HIV-1, Testpack, Serodia HIV-1, and HIV-1/2 RTD) were evaluated and results compared with standard enzyme **immunoassay** (EIA) and Western blot results (phase 1). Further evaluation consisted of prospective testing of routine specimens at regional (phase 2; n = 900) and rural, peripheral laboratories (phase 3; n = 1266) throughout Honduras with selected assays. Results: Sensitivity and specificity were calculated for each assay and combination of assays for each phase to evaluate the effectiveness of the WHO alternative testing strategies. All tests in all phases were gt 99% sensitive after correcting for technical errors, with two exceptions (SUDS, phase 1; HIVCHEK, phase 3). In phase 3, where the testing **algorithm** was **diagnostic**, several combinations of assays were 100% sensitive and specific using WHO strategy II or III. For the Honduras Ministry of Health, the combination of Retrocell and Genie was found to be equally sensitive, more specific (no indeterminate results), and less expensive than EIA/Western blot. Conclusion: Combinations of rapid, simple HIV antibody assays provide sensitivity and specificity performance comparable to EIA/Western blot. Application of these combinations in the WHO alternative testing strategies provides an inexpensive and effective method of determining HIV status. Assay combinations using these strategies can be easily performed in small, rural laboratories and have been implemented in routine HIV screening in Honduras.

L13 ANSWER 16 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 97:452416 PROMT
TITLE: A **Diagnostics** Industry Roundtable: Where is Growth? Part 1
AUTHOR(S): Diller, Wendy
SOURCE: In Vivo, (Jul 1997) pp. 5. ISSN: 0258-851X.
LANGUAGE: English
WORD COUNT: 1783

*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB Four top executives agree on continuing consolidation and the necessity of pharmaceutical and device collaborations. Research is another matter.

* The unprecedented wave of mergers seems likely to continue as **diagnostics** companies try to eliminate excessive capacity from the market and expand their breadth of products in order to attract large-volume buyers.
* Executives see attractive opportunities in new proprietary markers, particularly in genetic testing, cancer **diagnostics**, drug monitoring and susceptibility testing.
* But the costs and risks of such biologically-based R&D arouse strategic disagreements between those who favor incremental improvements and those going for more significant advances.
* Industry executives increasingly are seeking collaborations with non-traditional partners in order to integrate information and exploit the full value of **diagnostic** tests.

From the acerbic comments of industry consultant and pathologist Robert DeCresce to offhanded observations about the declining number of residents in pathology training programs, the atmosphere at this year's American Association for **Clinical Chemistry** (AACC) could best be described as plaintive. The annual meeting, which was held the third week in July in Atlanta, drew more than 12,000 exhibitors, buyers and scientists. But it was a subdued affair compared to previous years, with fewer new product launches, fewer big corporate bashes, and a greater educational emphasis on the business aspects of laboratory science.

The mood reflected the **diagnostics** industry's ongoing turmoil, as it struggles to cope with declining reimbursement, the consolidation and continuing reorganization of its core customer base, and almost commodity-like pricing pressure in major market segments like **clinical chemistry**, hematology, and subsets of **immunoassay**. Government efforts to reduce testing volume by requiring clinicians to code separately for certain tests that previously could be ordered as part of a panel have been in effect for some months now and are taking a heavy toll on hospital and reference labs. Large buying groups, which contract for supplies on behalf of member hospitals, are consolidating, as are hospital laboratories. And, at best, the major **diagnostic** segments face low single-digit growth at least through the turn of the century. The business overall is expected to grow worldwide only 4% through 2000, according to Boston Biomedical Consultants.



L13 ANSWER 17 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 97:325403 PROMT
TITLE: The Rage to Consolidate in **Diagnostics**,

Searcher : Shears 308-4994

Part 1
Consolidation is speeding up, driven by increasing costs of infrastructure and R&D

AUTHOR(S): Diller, Wendy
SOURCE: In Vivo, (Apr 1997) pp. 3.
ISSN: 0258-851X.
LANGUAGE: English
WORD COUNT: 1892
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB As **diagnostic** industry infrastructure and R&D costs escalate and buyers gain more clout, manufacturers are looking to consolidation for long-term viability and growth. Faster growth is the motivation for market leaders, while size and operating efficiencies are driving other deals.
* Consolidation is speeding up, driven by increasing costs of infrastructure and R&D, with a sense of urgency added by concerns about profitability due to continued pricing declines and only modest increases in testing volume worldwide.
* The gap between market leaders and lesser players is growing, with much of the consolidation activity occurring among the second and third tier players.
* The concentration of power in the hands of a few buyers in the US is having a powerful impact on companies as they plan their strategies going forward.
* Buying market share in slow growing or flat businesses may be necessary but it does not in and of itself lead to acceptable profitability. Acquisitions for growth and getting customers to think differently about the role of testing are more likely to increase long-term economic value.
In January of this year, the national hospital alliance Premier Inc. announced the winners of its contract for **clinical chemistry**. The contract had been particularly important because it would cover all of Premier's 1,800 member hospitals, or about a third of hospitals in the US. Moreover, only one chemistry company would win--so bidders cut prices to the bone, figuring to make their money back on volume. But instead of choosing one supplier, Premier chose three, giving it the best of both worlds--heavy discounts and a choice of vendors.
Upset over the process and the pricing, each of the three winners, Johnson & Johnson Clinical **Diagnostics**, Corange Ltd. subsidiary Boehringer Mannheim Corp., and Dade International Inc., then had to get Premier's members to favor its instruments over the others. Meanwhile, the losers set about trying to undermine Premier's ability to enforce compliance and spreading rumors about the details of the contracts, which some member hospitals have yet to see. Since Beckman Instruments Inc., the number two chemistry player, lost the bid, industry wags speculated that most members of the Premier committee which made the decision were from the Northeast, where Beckman is weakest, or, as is more likely, Beckman

wouldn't cave on pricing as much as its competitors.
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L13 ANSWER 18 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 97:307488 PROMT
TITLE: Has the FDA Changed Tumor Markers' Future?
SOURCE: Genesis Report-Dx, (1 Apr 1997) pp. N/A.
ISSN: 1061-2289.
LANGUAGE: English
WORD COUNT: 4700
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB Summary

In September 1996, the FDA changed its marketing clearance process for tumor markers. The agency reclassified markers from class III medical devices, for which approval requires the filing of a lengthy and timeconsuming premarket approval (PMA) application, to class II devices, for which the FDA can give clearance after reviewing the easier-to-prepare 510(k) application.
How will the reclassification affect the development and marketing of tumor markers?
The first possibility' is that reclassification will lead to the marketing of a large number of new tumor markers. In the first 6 months after the reclassification, the FDA received 20 new marketing approval applications for tumor markers, or about as many as there are markers currently available in the United States. However, at a recent conference on tumor markers sponsored by the American Association for **Clinical Chemistry**, a number of oncologists and authorities on cancer **diagnostics** predicted that other regulatoryand marketing factors will affect the development of tumor markers. Those factors include:
The reluctance of physicians and laboratory professionals to adopt the new markers. Physicians are often uninterested in markers for essentially untreatable cancers. Laboratorians may not want to use tumor marker assays because different assays for the same marker give different results.
The FDA's regulation of tumor markers has been eased, but not abandoned. A PMA is still required for tumor marker **immunoassay** systems that would be used to screen the general public or a high-risk population for the early detection of cancer or to do disease staging. In addition, a PMA is needed for tissue-receptor **assays**, **immunohistochemical** stains, and direct tests for oncogenes or other genetic markers associated with a predisposition to cancer.
Reimbursement from the government or private payers could theoretically be denied for a tumor marker test if it does not have a CPT/ICD code. Less than half of the currently used markers have the appropriate code.
Managed care organizations (MCOs) do not automatically approve the

use of or reimburse for a new tumor marker test solely because the test has received FDA approval. Instead, MCOs base their decisions on a review of the test's quality, cost, medical importance, and a comparison with current technology.
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L13 ANSWER 19 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 97:307492 PROMT
TITLE: Chiron **Diagnostics**: DNA Probes to Gas Analyzers
SOURCE: Genesis Report-Dx, (1 Apr 1997) pp. N/A.
ISSN: 1061-2289.
LANGUAGE: English
WORD COUNT: 6435
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB size.
Produce more analyses for each electrophoresis gel used in a sequencer.
Increase the throughput of sequencing systems by collecting more data in the same amount of time.
A small company, Visible Genetics Inc (VGI) (Toronto, Canada), is developing an ultrathin gel electrophoresis system that is much shorter than the gels used in the larger automated sequencing systems. The company claims its system can easily sequence a DNA chain of 300 nucleotides with a gel run of only 20 minutes, compared to the approximately 2-hour run time in the automated instruments.
In March 1997, VGI entered a research agreement with Consolidated Laboratory Services (Van Nuys, CA) to develop two **diagnostic** tests for HIV. The tests will be a quantitative viral load and a full sequence-based test that will employ VGI's single-tube sequencing and stratified matrix test methods.
The VGI approach may be quite useful in a research environment or in small laboratories with limited sequencing needs. However, VGI does not seem to address two salient issues - the problems of sample preparation and data analysis - of high-throughput sequencing. In order to see dramatic improvements in throughput efficiency, substantial systemwide advancements are necessary.
A dramatic increase in efficiency of DNA sequencing may be provided by a capillary gel electrophoresis technique being developed in the laboratories of S Yeung at Iowa State University (Ames, Iowa). This technique separates DNA fragments in a multichannel capillary electrophoresis unit that simultaneously detects all channels. According to Yeung, a 100-capillary system, or a system with 100 channels running simultaneously, operates about 24 times faster than the model 377 sequencer from Applied BioSystems. Yeung maintains that the technology could be easily scaled up to 1,000 capillaries operating simultaneously, a result that would achieve a gross

sequencing rate of 40 million bases per day. However, the system's sample preparation and data handling cannot adequately handle such high volumes. Iowa State University has licensed the technology to Premier American Technologies Corp (PATCO) (Belfont, PA). Other companies, including Applied BioSystems, are also developing capillary electrophoresis systems.

PATCO's gel electrophoresis system is designed to run 96 capillaries simultaneously. The process uses florescent dyes, making it similar to an Applied BioSystems gel electrophoresis product. In the PATCO system, the readout device is a charged-couple device camera. The camera continuously reads all 96 capillaries rather than scanning across the 96 capillaries, as is done by gel electrophoresis systems.

PATCO claims that the system is automated so that a technician can load the machine with six to eight 96-well trays, start the instrument, and return in 8 hours to collect the data. Therefore, if each well in the microwell plate contains a 400-base fragment to sequence, then at the end of an 8-hour shift, 230,000 bases of raw data would be collected.

The company expects the initial market to consist of laboratories performing de novo sequencing. This is a relatively large market because laboratories of pharmaceutical, biotechnology, genomics, and agricultural biotech companies are all conducting de novo sequencing for research and development. In the future, PATCO plans to extend sequencing analysis to clinical laboratories.

(Editor's Note: This is one of several articles that will appear in THE GENESIS REPORT/Dx on the **diagnostic** potential of DNA sequencing. Future articles will explore the **diagnostic** applications of the technology in more detail.)

Clarifications

The article on the 1996 MEDICA conference in the January 1997 issue of THE GENESIS REPORT/Dx identified the IMMULITE 2000 instrument from **Diagnostic** Products Corp (Los Angeles, CA) as the IMMULITE 2000 XXL and the IMMULITE XL. The correct registered, trademarked name is the IMMULITE 2000.

An article in the November 1996 issue stated that the QuickVue One-Step H pylori test from Quidel Corp (San Diego, CA) was the first H pylori test to be classified as waived under the Clinical Laboratory Improvement Act of 1988. The Quidel test, which uses serum samples to detect circulating antibodies to H pylori, was granted the waived status in October 1996. Serim Research Corp (Elkhart, IN) received the waived categorization in February 1996 for its Serim PyloriTek test, which detects the production of urease by H pylori in biopsy specimens.

And Almost Everything Else ...



L13 ANSWER 20 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 97:395116 PROMT
TITLE: DEVELOPMENTS IN BIOTECHNOLOGY--Feature: A profile of Genzyme Corporation
SOURCE: BioAccess, (1 Jun 1997) pp. N/A.
ISSN: 1356-3432.
LANGUAGE: English
WORD COUNT: 6367
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB ck

Genzyme Corp. recently acquired PharmaGenics and merged it with some of Genzyme's current programmes to create a new division called Genzyme Molecular Oncology. Genzyme will acquire PharmaGenics in exchange for shares of a new class of "tracking" stock intended to track the performance and reflect the value of Genzyme Molecular Oncology.

The chief reasons for using the tracking stock, which is not yet publicly traded, is to provide a vehicle for raising capital for the new division and to better enable the stock market to fully recognise the division's value. The company believes the division's full value will be recognised because tracking stock provides investors with a "pure play" in the division and gives the division greater visibility.

Another advantage of tracking stock is that Genzyme will remain a single tax entity, filing a consolidated return that will include the profits and losses of the General Division (Nasdaq:GENZ), the Tissue Repair Division (Nasdaq:GENZL), and the Molecular Oncology Division. Thus Genzyme will have a lower tax expense than would be the case if Genzyme Molecular Oncology were spun off as a separate corporation.

Also known as "letter stock", tracking stock was first employed in 1984 in General Motors' acquisition of Electronic Data Systems. A year later GM used tracking stock to acquire Hughes Aircraft. In the 1990s, USX Corp. issued tracking stocks for its steel, oil, and natural gas units, and the Pittston Company did the same for its mining and service divisions.mount of the operating losses of Tissue Repair. These benefits will decrease and eventually end as Genzyme Tissue Repair moves into profitability. This business will not carry forward its losses to offset future tax liabilities.



L13 ANSWER 21 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 96:126544 PROMT
TITLE: BIOCIRCUITS ANNOUNCES FIRST SHIPMENT OF IOS IMMUNODIAGNOSTIC TESTING SYSTEMS
SOURCE: PR Newswire, (4 Mar 1996) pp. 304NYM002.
LANGUAGE: English
WORD COUNT: 510

*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB SUNNYVALE, Calif., March 4 /PRNewswire/ -- Biocircuits Corporation (Nasdaq: BIOC) today announced the first sale and shipment of its IOS(TM) immunodiagnostic testing systems. The IOS system incorporates a low-cost, compact in-office test instrument and patented, disposable **assay** cartridges which allow **immunodiagnostic** testing to be performed in physicians' offices and at other points of patient care.

"With the sale and shipment of our IOS systems, we have achieved our original objective to be the first company to introduce an easy-to-use, low-cost **immunoassay** system, capable of performing a large menu of tests, to the physicians' office market. The sale of these units marks the emergence of Biocircuits as a full-scale operating company addressing a large and unserved market," said John Kaiser, President and Chief Executive Officer of Biocircuits. "Exactly two years ago this week, Biocircuits announced that it would reformulate its assay cartridge technology, replacing the original lipid/polymer molecular membrane with a florescence generating substrate. Within this two-year period, we successfully redesigned our IOS system, established operating and distribution capabilities and obtained necessary regulatory clearance to bring the product to market."

Biocircuits is targeting the approximately 41,000 small to medium-sized physician office practices and free-standing alternate site laboratories, currently performing in-office **clinical chemistry** and/or hematology testing, but which do not currently have an immunodiagnostic testing capability. These sites are CLIA licensed to perform moderately complex testing. The Company is selling the IOS system through a national **network** of distributors who have extensive experience in placing medical testing equipment in physicians' offices. The IOS system is approved for moderately complex testing.



L13 ANSWER 22 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 96:429214 PROMT
TITLE: Miniaturized **Diagnostics** Grow in Importance
SOURCE: Genesis Report-Dx, (1 Jul 1996) pp. N/A.
ISSN: 1061-2289.
LANGUAGE: English
WORD COUNT: 3318

*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB Summary

Until recently, the development of microtechnology for **diagnostics** applications has focused primarily on molecular **diagnostics** such as DNA probes and DNA sequencing-based **diagnostics**. To date, most of this research into developing the so-called "laboratory on a chip" has addressed only a few

aspects of molecular **diagnostic** testing. Separate instrumentation would be required to complete the whole **diagnostic** process.

Two companies are independently pursuing a different approach. Caliper Technologies and Soane BioSciences are developing totally integrated systems for their microchip technologies. These systems would perform every step of a **diagnostic** process, from sample processing through data analysis, and would be capable of conducting a range of **diagnostic** tests, including **clinical chemistries**, **immunoassays**, and molecular **diagnostics**. Neither company is developing new technology such as DNA probes. Rather, the novel approaches attempt to link existing **diagnostic** scienceand technology into a new format.

The systems being developed by Caliper and Soane would consist of microfiuidic integrated circuits that would be microscopic versions of liquid-handling and biochemical-processing devices such as pumps, valves, volume-measuring devices, reactors, extractors, and separation systems. Both companies have plans to connect their devices to form a complete chemical processing system on the surface of a microchip. A sample would therefore be processed and tested as it passes through etched microchannels, and the procedure could be completed in seconds on a chip the size of a dime.

The primary benefits of fluidic microchips would be a better analytical performance than is possible with current **diagnostic** technologies and a lower cost for operation and manufacture. However, both companies must overcome several technical obstacles before the new technologies can be commercialized. These obstacles will require the development of new methods for pipetting of picoliter-size samples, separating functions-on the microchip, and validating and testing microchip manufacturing.

Caliper and Soane estimate that their products will reach the research market in less than 2 years and the clinical **diagnostics** market within 3 to 5 years, if the FDA approves the technology.



L13 ANSWER 23 OF 38 BIOSIS COPYRIGHT 1999 BIOSIS

ACCESSION NUMBER: 1996:62569 BIOSIS

DOCUMENT NUMBER: PREV199698634704

TITLE: Predictive values of **immunoassays** of the second generation in the **diagnosis** of an infection with HIV-1.

AUTHOR(S): Rodriguez, Orfelina; Argote, Esther; Lopez, Gricel; Nibot, Carmen

CORPORATE SOURCE: Cent. de Invest. Cientificas de la Defensa Civil, Lab. de Invest. del SIDA, Apartado 23031 Habana 14, Ciudad de La Habana, Habana Cuba

SOURCE: Biotecnologia Aplicada, (1995) Vol. 12, No. 2, pp. 112-114.
DOCUMENT TYPE: Article
LANGUAGE: Spanish
SUMMARY LANGUAGE: Spanish; English

AB The predictive values of the **immunoassays** not only depend on the sensitivity and specificity, but also on the HIV infection prevalence. It is also an important parameter in the evaluation of the assays for the detection of antibodies to HIV. That is why the objective of this work was to determine the predictive values of two **immunoassays** of national production: RECVIH and Recombinant UMELISA HIV. The positive predictive values were 88.12% for the RECVIH and 93% for the Recombinant UMELISA HIV and the negative predictive values remained 100% in a population with an HIV infection prevalence of 6%. The positive predictive values were 0.69% and 1.23% for RECVIH and Recombinant UMELISA HIV **immunoassays** in a population with a serologic rate of 0.006%. These factors together with the high sensitivity and specificity of these **immunoassays** allow their use in the lab **network** for serologic **diagnosis** of HIV-1.

L13 ANSWER 24 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 95:388619 PROMT
TITLE: American Companies in Japan: PRECISION AND MEDICAL EQUIPMENT
SOURCE: Japan-U.S. Business Report, (1 Sep 1995) pp. N/A.
LANGUAGE: English
WORD COUNT: 824
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB Semiconductor manufacturing equipment maker GASONICS INTERNATIONAL CORP. has paid an undisclosed price for TEKISCO CO., LTD., a producer of low-pressure chemical vapor deposition equipment for polysilicon-on-quartz applications for flat panel displays. The acquisition gives the San Jose, California company a manufacturing presence in Japan, where virtually all of the worlds FPDs are made. Tekiscos operations, including its plant in Atsugi, Kanagawa prefecture, will be folded into GaSonics recently established Japanese subsidiary. KISHIMOTO SANGYO CO., LTD., Tekiscos former parent, will extend marketing support over the near term.
FAS-TECHNOLOGIES, INC. is gaining business among makers of liquid crystal displays and multichip modules for its FAS-Coat liquid extrusion coating system. The system provides precision coating of photoresists and polyimides onto LCD and MCM substrates. The Dallas, Texas company says its technology eliminates 80 to 90 percent of the processing fluid waste typical of the standard spin-coating method. Projected Japan sales are $1.3 million for 1995 and $6.3 million next year.
COMPETITIVE TECHNOLOGIES INC. and its Japanese affiliate, INNOVATION

PARTNERS INTERNATIONAL, have licensed the Westport, Connecticut firms Plasma Display Energy Recovery technology to a Japan-based venture between PLASMACO INC. and an unnamed Japanese consumer electronics company. The Highland, New York manufacturer and its partner are working on the development of large, color plasma-based FPDs for use in both television and computer applications. Competitive Technologies received a fee of $300,000 for the technology; it also will earn royalties on any sales.
FOUR PI SYSTEMS, a San Diego, California-based subsidiary of HEWLETT-PACKARD CO., will put on the market in November through HPs local unit the 5DX Series of process control systems. The series, priced at $421,100 and up, uses three-dimensional cross-sectional X-ray imaging to analyze solder joints for defects on single-and double-sided printed circuit board assemblies.
The leading U.S. manufacturer of rapid prototyping equipment, 3D SYSTEMS, is cutting prices by 16 to 20 percent on the two models it currently sells in Japan. The SLA250, cut to $368,400, and the SLA500, lowered to $684,200, use StereoLithography technology to create 250-millimeter-square and 500-millimeter-square three-dimensional prototypes, respectively.


L13 ANSWER 25 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 95:389651 PROMT
TITLE: BIOCIRCUITS RECEIVES FDA CLEARANCE TO MARKET FIRST TWO ASSAY CARTRIDGES FOR IOS(TM) IMMUNODIAGNOSTIC TESTING SYSTEM
SOURCE: PR Newswire, (27 Nov 1995) pp. 1127NYM017.
LANGUAGE: English
WORD COUNT: 581
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB SUNNYVALE, Calif., Nov. 27 /PRNewswire/ -- Biocircuits Corporation (Nasdaq: BIOC) today announced it has received clearance from the U.S. Food & Drug Administration (FDA) to market the first two assay cartridges, a combined T4 and T Uptake assay and a T4-only assay, for its IOS(TM) immunodiagnostic testing system. The IOS system incorporates patented, disposable assay cartridges designed exclusively for use with a low-cost, compact test instrument to perform immunodiagnostic testing in physicians' offices and at other point-of- care sites. The IOS test instrument is currently in FDA review for marketing clearance. T4 and T Uptake assays are commonly used by physicians to assess thyroid dysfunction, and are the first of a broader menu of assays the Company plans to offer for the IOS system.
"We are pleased to receive marketing clearance for our first two assay cartridges and hope to receive FDA clearance of our IOS testing instrument before the end of the year," said John Kaiser,

President and Chief Executive Officer of Biocircuits. "Once the IOS instrument is cleared for marketing, we will immediately begin training our recently established distributor sales force and we expect to begin shipping product in early 1996."
In June 1995, Biocircuits filed two 510(k) applications with the FDA, one for the IOS instrument and another for the cartridge for the combined T4/T Uptake assay with a calculated Free Thyroxine Index (FTI). The Company filed a third 510(k) for the T4-only assay cartridge in August 1995.
"The high volume of T4 and T Uptake assays requested by office-based physicians each month creates considerable market potential for a product like IOS that can quickly and cost-effectively perform these tests in the office setting," said Byron Hewett, Biocircuits' Vice President of Sales and Marketing. "We expect physician acceptance and use of IOS to increase as we expand the system's testing menu to include additional assays currently in development."
Biocircuits is developing additional cartridges for other tests commonly performed in the physicians' office setting, including a test for thyroid-stimulating hormone (TSH) to assess thyroid dysfunction, a Serum Pregnancy test to **diagnose** pregnancy, and a Quantitative hCG test to track the progress of early pregnancies.


L13 ANSWER 26 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 95:399069 PROMT
TITLE: BIOCIRCUITS RECEIVES FDA CLEARANCE TO MARKET IOS IMMUNODIAGNOSTIC TESTING INSTRUMENT
SOURCE: PR Newswire, (4 Dec 1995) pp. 1204NYM022.
LANGUAGE: English
WORD COUNT: 609
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB SUNNYVALE, Calif., Dec. 4 /PRNewswire/ -- Biocircuits Corporation (Nasdaq: BIOC) today announced that the U.S. Food & Drug Administration (FDA) has cleared the Company's IOS(TM) immunodiagnostic testing instrument for marketing and sale in the U.S. The IOS system incorporates a low-cost, compact test instrument and patented, disposable assay cartridges and is the first cost-effective, easy-to-use immunodiagnostic system available for use in physicians' offices and at other point-of-care sites.
Biocircuits recently received FDA clearance for its first two assay cartridges, a combined T4 and T Uptake assay with a calculated Free Thyroxine Index (FTI), and a T4-only assay. These assays are commonly used to assess thyroid dysfunction, and are the first of a broader menu of assays the Company plans to offer with the system.
"FDA clearance of our IOS system for marketing is a critical milestone that marks the emergence of Biocircuits from a research & development start-up to a full-scale operating company with product

sales potential," said John Kaiser, President and Chief Executive Officer of Biocircuits. "We plan to begin training our recently established distributor sales force immediately and expect to start shipping product in early 1996."
The Company plans to target the estimated 45,000 small to medium-sized medical practices, comprising 1 to 8 physicians, which currently perform in-office **clinical chemistry** and/or hematology testing, but which do not currently have an immunodiagnostic testing capability. Since currently available immunodiagnostic systems cost $25,000 to $50,000 and require operation by highly-skilled laboratory technicians, they are, for the most part, only cost-effective for large laboratories that perform a high volume of tests. Typically, the physician and patient must wait several days to receive test results. By comparison, the IOS system can provide accurate test results in 20 to 30 minutes and the Company expects the up-front instrument costs will be approximately $6,000.


L13 ANSWER 27 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 96:28174 PROMT
TITLE: Transforming Transactions
SOURCE: In Vivo the Business & Medicine Report, (1 Oct 1995) pp. 3.
ISSN: 0258-851X.
LANGUAGE: English
WORD COUNT: 3957
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB As customers look for product breadth in their suppliers, some creative device players are using deals to redefine their product offerings, customers, and themselves.
Part II of a two-part article on alliances and acquisitions in medical devices. Part I, "Device Startups and Alliances," appeared in the July/August 1995 issue.
*Customers are looking to fewer manufacturers for wider varieties of products in their drive to reduce costs; traditional device markets are thus shrinking into niches.
* To avoid marginalization, companies are re-positioning their core businesses to add a set of informational, therapeutic or logistical values which would allow them to compete with what might be called traditional product breadth.
* Alliances and acquisitions will be the key strategic tools of these re-positionings; the deals will pair partners in very different businesses (e.g., high-tech devices and distribution, in vitro **diagnostics** and patient monitoring) and with very different economics (disposables and capital equipment).
If there is a single imperative to dealmaking in medical devices it is breadth--to learn to appeal to consolidating buyers as one-stop

shopping solutions, if not across broad supply categories, at least within defensible niches. The problem is: most companies aren't one-stop shopping solutions; they are niche players. And as the provision of care migrates from easy-to-target hospitals to integrated systems featuring hospitals as well as clinics, doctor's offices and homes, even companies which had formerly been relatively broad-based suppliers now find they can be frustratingly narrow in scope.

Dealmaking--acquisitions and alliances--look to be the easiest way to broaden a company's product offerings. When United States Surgical Corp. revolutionized the surgical market with its laparoscopy instrument, the Ethicon Inc. unit of Johnson & Johnson was forced to building what is now the market-leading laparoscopic instruments business based on products in-licensed from Symbiosis Corp. and Olympus America Inc.

By RL

Table shows the consolidating world medical devices



L13 ANSWER 28 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 95:230487 PROMT
TITLE: Abbott's About Face: What It Means for the Physician's Office Market
Integrated management results to an operating gross profit of $73.2 in 1995
SOURCE: In Vivo the Business & Medicine Report, (May 1995) pp. 17.
ISSN: 0258-851X.
LANGUAGE: English
WORD COUNT: 4112
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB *In shifting its small group practice **diagnostics** business from a direct sales force to an outside distributor, Abbott is responding to a tougher business environment, but it also sees opportunities for growth.

*As a result of marketplace changes, distributors and manufacturers are also rethinking their relationships with each other and appear to be galvanized by the breadth and exclusivity of the Abbott-PSS deal.

*The mid-range group practice remains a viable customer for manufacturers of flexible instruments that offer comparatively low costs per test. But companies need to revise their sales pitch from focusing on the profitability to physicians of doing in-office testing to the outcomes and total system cost of on-site testing.

When Abbot Laboratories announced last month that it had signed an exclusive agreement for Physician Sales & Service Inc. to distribute its **diagnostics** products for smaller physicians' offices, it jolted competitors. The deal was huge--it affects products that

account for about $100 million in revenues. It also was a departure for Abbott, which traditionally has sold all of its products direct. Furthermore, the agreement was exclusive, highly unusual for distributor-vendor relationships in the **diagnostics** or an industry. Was Abbott losing interest in selling to smaller group practices? The business has been battered in recent years, first by the implementation of burdensome CLIA regulations, then by uncertainties surrounding health care reform and managed care. Perhaps, wondered competitors, Abbott was delegating a declining business to a lower cost outside sales force in order to concentrate on the more vibrant larger group practice and hospital customers. Table shows physician sales and service inc. financial performance


L13 ANSWER 29 OF 38 BIOSIS COPYRIGHT 1999 BIOSIS
ACCESSION NUMBER: 1995:76511 BIOSIS
DOCUMENT NUMBER: PREV199598090811
TITLE: Serotoninergic control of gonadotrophin and prolactin secretion in women.
AUTHOR(S): Ulrich, Uwe (1); Nowara, Ingrid; Rossmanith, Winfried G.
CORPORATE SOURCE: (1) Dep. Obstet. Gynecol., Div. Reprod. Endocrinol. XD-44, Univ. Wash. Sch. Med., 4225 Roosevelt Way NE, Seattle, WA 98105 USA
SOURCE: Clinical Endocrinology, (1994) Vol. 41, No. 6, pp. 779-785.
ISSN: 0300-0664.
DOCUMENT TYPE: Article
LANGUAGE: English
AB Objective: Due to conflicting observations from previous investigations, the role of serotonin (5-HT) in the regulation of the human menstrual cycle has not been clearly established. We have therefore investigated the possible participation of 5-HR in the control of gonadotrophin and PRL secretion in women, using the potent 5-HT-3 receptor antagonist ondansetron as a pharmacological probe. Design: Serum profiles of LH, FSH and PRL were obtained in 9 normally cycling women during a control and a treatment cycle, during which ondansetron (8 mg orally) was administered daily. On day 10 of both cycles, the serum pulsatility of LH, FSH and PRL was assessed by frequent blood sampling (at 10-minute intervals for 10 hours). Pituitary responsiveness was tested by administration of a GnRH bolus (25 mu-g i.v. after 8 hours). Measurements: LH, FSH and PRL were serially determined in all blood samples by **immunofluorescence assays**. The resulting hormone data arrays were searched for significant fluctuations by the Cluster pulse **algorithm**. Results: Compared with control cycles, the temporal organization and the endocrine characteristics of the treatment cycles remained virtually unaltered. Serotonin antagonism did not noticeably affect the LH pulse attributes

(frequencies, interpulse intervals, amplitudes). Although FSH amplitudes declined markedly (P lt 0.05), the remaining pulse attributes were unchanged. A clear increase (P lt 0.05) in the PRL pulse frequency was noted, while PRL pulse amplitudes tended to increase (P = 0.1). Gonadotrophin and PRL release in response to GnRH administration was unaltered by ondansetron treatment. Conclusions: Serotoninergic blockade by a selective 5-HT-3 receptor antagonist failed to modify pulsatile LH secretion, but induced distinct changes in episodic FSH and PRL secretion. Since the pituitary gonadotrophin and PRL responsiveness remained unaltered during 5-HT-3 receptor blockade, the observed alterations in the FSH and PRL secretion presumably relate to altered hypothalamic regulation of these pituitary hormones. Thus, the central regulation of pulsatile FSH and PRL release in women appears to involve 5-HT-3 receptor-mediated processes.

L13 ANSWER 30 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 95:22274 PROMT
TITLE: Bain Capital's Strategy in Health Care
SOURCE: In Vivo the Business & Medicine Report, (Dec 1994) pp. 9.
ISSN: 0258-851X.
LANGUAGE: English
WORD COUNT: 4222
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB When Baxter International Inc. announced last fall that it had sold its **diagnostics** division, the deal was striking for one reason in particular. Not because of the price, which Wall Street considered to be fair at $448 million, but because it involved a financial buyer, unusual in health care, taking a gamble on a health care company that had been hard to sell. Moreover, that buyer, Bain Capital, heretofore not highly visible in the industry, had just recently bought another big medical device business, Physio-Control, from Eli Lilly & Co. What's Bain Capital up to?

Traditionally, financial buyers have shied away from investing in mature but technology-intensive health care companies. They have been daunted by the regulatory oversight and heavy dependence on expensive, risky R&D programs. Perhaps the biggest obstacle, however, has been the lack of properties available at bargain prices, a phenomenon that was likely to continue as long as strategic buyers were willing to bid at premium prices.

But the makeup of the companies doing the buying and selling is changing. Large pharmaceutical companies, once key strategic buyers, are undergoing fundamental restructuring and spinning off peripheral divisions. Other corporations involved in health care face pressure to improve their performance and aren't stepping into their shoes as acquirers; non-health care entities that favored the field in the 1980s now steer clear of it because of the uncertainties. The

result is that an increasing number of health care businesses, some troubled, some successful, are up for sale and fewer traditional strategic buyers are seeking them out.



L13 ANSWER 31 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 94:448813 PROMT
TITLE: **Diagnostics**: Just Who Is the Customer?
SOURCE: In Vivo the Business & Medicine Report, (Jul 1994) pp. 10.
ISSN: 0258-851X.
LANGUAGE: English
WORD COUNT: 3292
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB Change was in the air at last month's American Association of **Clinical Chemistry** meeting in New Orleans. Both customers and manufacturers seemed willing to acknowledge and respond to health care reform, and in particular the impact of managed care - phenomena already well accepted in pharmaceuticals and medical supplies circles. An early morning seminar for laboratorians on managing health care costs was filled to standing capacity, as was a much larger symposium on health care reform. Exhibitors extolled the value of their products in finding solutions to the political and financial pressures their customers face. Instead of talk about labor shortages in the laboratory, concerns centered on using automation to increase laboratory productivity and to decrease staffing. And discussions regarding new markers, while centering on the science, included at least superficial mention of cost effectiveness.

The big companies are still eager to display more and ever larger automated immunochemistry and **clinical chemistry** instruments with more bells and whistles, capable of running more analytes. But they are swimming in uncertain waters because, at least in the short term, it is not clear who their customers are or will be in the future - the hospital alliances, with their central and satellite laboratories, the independent central laboratory in the hospital, the large regional reference laboratory or its nationwide parent, and who within those organizations will have ultimate say over purchasing decisions. 'The structure of the buyer's industry is changing. The opportunity is being driven by how to sell to this industry, not by growth in the industry,' says Larry McGrath, president of McGrath & Associates Inc, a consulting firm in Grass Valley, CA.

An area of testing that received much attention was cardiovascular markers. A new generation of tests is not only changing the laboratorian's role in **diagnosing** heart attacks and monitoring cardiac patients, but also providing one of the few areas of growth. If the markers really work, they could offer substantial

health cost savings, reducing the number of misdiagnosed heart attacks (and therefore the number of inappropriately treated patients).

Cardiac markers represent one of the few growth areas in **diagnostics**, not only for manufacturers but also for their customers. The market opportunity is theoretically huge. Four million Americans a year appear at emergency departments for ches



L13 ANSWER 32 OF 38 EMBASE COPYRIGHT 1999 ELSEVIER SCI. B.V.

ACCESSION NUMBER: 93145678 EMBASE
DOCUMENT NUMBER: 1993145678
TITLE: International Federation of **Clinical Chemistry** standardization project for measurements of apolipoproteins A-I and B. III. Comparability of apolipoprotein A-I values by use of International Reference Material.
AUTHOR: Marcovina S.M.; Albers J.J.; Henderson L.O.; Hannon W.H.
CORPORATE SOURCE: Department of Medicine, Northwest Lipid Research Lab., University of Washington, 2121 N. 35th St.,Seattle, WA 98103, United States
SOURCE: Clinical Chemistry, (1993) 39/5 (773-781).
ISSN: 0009-9147 CODEN: CLCHAU
COUNTRY: United States
DOCUMENT TYPE: Journal; Article
FILE SEGMENT: 018 Cardiovascular Diseases and Cardiovascular Surgery
029 Clinical Biochemistry
LANGUAGE: English
SUMMARY LANGUAGE: English

AB In the third phase of the International Federation of **Clinical Chemistry** (IFCC) study for the standardization of apolipoprotein (apo) measurements, the preparation SP1-01, selected as the candidate international reference material for apo A-I, was investigated for its ability to transfer an accuracy-based value to the **immunoassay** calibrators and to produce comparability of the values for patients' samples. An apo A-I value of 1.50 g/L (SD 0.08 g/L) was assigned to SP1-01 by a highly standardized RIA calibrated with purified apo A-I for which the mass value had been determined by amino acid analysis. According to a common detailed protocol, the participants transferred the mass value from SP1-01 to the calibrator of each method. To confirm that uniformity of calibration ensures comparability of the values over a wide range of apo A-I values, each laboratory analyzed 50 fresh-frozen samples from individual donors, using an approach similar to that adopted by the Cholesterol Reference Laboratory **Network**. The consensus mean value for each sample was in excellent agreement with the value assigned by

the Northwest Lipid Research Laboratories, with the average absolute bias between assigned and consensus value being 0.01 g/L. The among-laboratory CV on each of the 50 samples ranged from 2.1% to 5.6% (mean 3.6%), demonstrating that comparable apo A-I results can be obtained by a variety of immunochemical methods through the use of certified reference material. Based on the results obtained in these studies, SP1-01 has been approved as Apolipoprotein A-I International Reference Material by the World Health Organization.

L13 ANSWER 33 OF 38 EMBASE COPYRIGHT 1999 ELSEVIER SCI. B.V.
ACCESSION NUMBER: 93213304 EMBASE
DOCUMENT NUMBER: 1993213304
TITLE: Standardization of hapten immunoprocedures: Total cortisol.
AUTHOR: Gosling J.P.; Middle J.; Siekmann L.; Read G.
CORPORATE SOURCE: Department of Biochemistry, University College,Galway, Ireland
SOURCE: Scandinavian Journal of Clinical and Laboratory Investigation, Supplement, (1993) 53/216 (3-41). ISSN: 0085-591X CODEN: SCLSAH
COUNTRY: United Kingdom
DOCUMENT TYPE: Journal; Conference Article
FILE SEGMENT: 003 Endocrinology
026 Immunology, Serology and Transplantation
029 Clinical Biochemistry
037 Drug Literature Index
LANGUAGE: English
SUMMARY LANGUAGE: English
AB The broad objectives of this report are to enhance the clinical utility of the results of hapten measurement immunoprocedures by encouraging standardization of the procedures. It was decided to restrict the subject of the report to one analyte, and cortisol was chosen because of its **diagnostic** importance, the need for improved comparability with routine procedures, and its relevance to many other analytes. Therefore, the immediate objectives are to improve the clinical utility of total serum cortisol concentrations measured on different occasions and in different laboratories, to make **diagnostic** reference intervals more reliable and widely applicable, and to improve **diagnostic** accuracy by: Improving the agreement between results from reference measurement procedures and the results obtained with normal routine immunoprocedures for the measurement of total serum cortisol, and hence the comparability of routine results; and Reducing the susceptibility of the immunoprocedures to crossreactivity and interference. It is recognized that good comparability of results depends on procedures which are specific, properly calibrated and validated, and that the most important factors are resistance to crossreactants and interferants. Analytical goals for cortisol immunoprocedures are zero bias for 'all' samples with respect to a

reference procedure, with the total analyticl standard deviation equal to, or less than, half the within-individual standard deviation for cortisol, or 7.6% according to a recent estimate. To these ends the group proposes the following measures: 1. An international **network** of reference laboratories for cortisol measurement should be established, and progressively developed to include other hapten analytes. The services of the participating laboratories would be necessary to make feasible other recommendations listed below. 2. Procedures should be comprehensively validated, including a thorough crossreactivity study with the results presented to indicate the possible significance of each crossreactivity, a direct comparison of results with those obtained by a reference procedure for an adequate number of varied fresh/frozen patient samples, and suitable clinical validation studies. 3. External quality assessment schemes should assess participating laboratory performance against reference procedure values, and not consensus values related to values determined by any group of participating procedures. They should also assess the ability to determine added standard and to resist common interferants. 4. Master calibrators for use in the production of calibrators included in commercial kits, and formulated identically to these, should be certified with at least one reference measurement procedure, so that the concentrations of analyte in calibrators can be traced back to concentrations determined by a reference procedure. 5. Experimental studies on immunoprocedures for cortisol (and other hapten analytes) to establish preconditions for better standardization and comparability of results should be encouraged. Briefly, this report reviews the endocrinology of cortisol and the clinical applications of its determination. The methodology of cortisol determination is disucssed with emphasis on the performance characteristics of current immunoprocedures. The characteristics of reference materials and reference methods are described, and validation procedures are extensively discussed.

L13 ANSWER 34 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 92:565252 PROMT
TITLE: Boehringer Mannheim Acquires Microgenics - Summary
SOURCE: Genesis Report-Dx, (Jan 1992) pp. N/A.
ISSN: 1061-2289.
LANGUAGE: English
WORD COUNT: 1839
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB In the June 1991 issue of The Genesis Report (TM)/Dx, we presented an in depth analysis of CEDIA (R), the novel reagent technology developed by the Microgenics Corporation. In October 1991, Boehringer Mannheim, one of the world's premier **diagnostic** companies and a key partner of Microgenics, signed a letter of

intent to purchase Microgenics. The acquisition ensures Boehringer continued access to CEDIA for its Hitachi large chemistry analyzers. More important, perhaps, it enables the company to field even smaller instruments with CEDIA **immunoassay** capability, allowing Boehringer to cover both ends of the **immunoassay** market. In return, Boehringer brings their reagent division's strength in reagent stability to address the most prominent shortcoming of the CEDIA technology, the relatively short stability of the reconstituted reagents.
Potentially, the addition of Microgenics and the CEDIA technology can significantly enhance Boehringer's business. The acquisition gives Boehringer control over the development of CEDIA technology as well as full access to all aspects of the technology. This puts Boehringer in a position to direct product development efforts and specify the applications, including those other than open channel chemistry analyzers. Ultimately, Boehringer could control a number of immunodiagnostic market segments: drug monitoring (TDM and DOA), thyroid, cancer, and anemia.


L13 ANSWER 35 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 92:614754 PROMT
TITLE: Managed Care And Its Impact On The **Diagnostics** Industry
SOURCE: In Vivo the Business & Medicine Report, (Oct 1992) pp. 8.
ISSN: 0773-1398.
LANGUAGE: English
WORD COUNT: 3433
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB Though they expect the impact to increase, most **diagnostic** companies have yet to quantify the impact of managed care on their business or to treat it as a separate market.
Managed care's impact is still unclear. It could increase price discounting and competition and, at the same time, create opportunities for tests that **diagnose** diseases earlier.
Cost effectiveness analyses will be increasingly important in selling **diagnostic** products as managed care takes off.


L13 ANSWER 36 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 92:548504 PROMT
TITLE: Hematology Analyzers: More Changes Coming? - Changing the Hematology Market
SOURCE: Genesis Report-Dx, (May 1992) pp. N/A.
ISSN: 1061-2289.

LANGUAGE: English
WORD COUNT: 1689
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB In the late 1980s, Technicon Instruments introduced the first laser analyzers with 5-part differentials. Technicon's H-1E and, later, its H-2 were the first analyzers which could provide the percentage and total count for the 5 types of WBCs. Lifshitz noted that the H-1 also maintains the differential for 24 hours. This, said Lifshitz, is "a critical factor for commercial labs which wouldn't even receive a specimen until 12 hours after collection." Given these advantages, the H-series was an immediate success: Technicon sold an estimated 250 to 350 units the first year it was available. However, Technicon's products reportedly encountered reliability problems, and their success proved short-lived.
Scott Fithian, an independent consultant in Allentown, PA, and previously vice president, marketing at Serono Baker **Diagnostics** said, "The Technicon H series was regarded as the reference automated 5-part differential method using staining and lasers. But, the Technicon H series analyzers have never been reliable. Back-up instruments never had the same (advanced) technology, but the back-up instruments were being run 60% of the time in many laboratories. I've heard that the H-1 analyzers averaged 2 (service) calls per week. Coulter has lots of references from laboratories which were frustrated while trying to implement the H-1."
One hospital pathologist added, "Three years ago when Technicon launched the H-1, our facility was told that Technicon could not supply reagents since the only factory worldwide making the hematology reagents had a batch failure. We had to stop using the analyzer. However, in terms of reliability, Technicon has done much better with the H-2 (a later model) than the H-1."


L13 ANSWER 37 OF 38 PROMT COPYRIGHT 1999 IAC

ACCESSION NUMBER: 92:567152 PROMT
TITLE: Glucose Monitoring: First Noninvasive **Diagnostic** Technique
SOURCE: Genesis Report-Dx, (Sep 1992) pp. N/A.
ISSN: 1061-2289.
LANGUAGE: English
WORD COUNT: 2983
*FULL TEXT IS AVAILABLE IN THE ALL FORMAT*

AB Summary
Noninvasive and less invasive **diagnostic** technologies have the potential to offer faster testing which would also be easier to administer and less painful to the patient. The many types of non-and less invasive techniques being developed range from

refinements of **diagnostic** standbys, such as **immunoassays**, to new imaging technology.
One application of noninvasive technology which is attracting extensive research is the monitoring of blood glucose levels in diabetics. Of all the noninvasive technologies under development, noninvasive blood glucose monitoring appears to be the closest to commercialization.
There is a clear need for noninvasive technology in this area. Currently, many diabetics use a variety of self-administered techniques for detecting their glucose levels, which are crucial indicators of the status of their disease. Although these techniques are accepted by both diabetics and doctors, they have a serious drawback. Nearly all obtain blood by a painful prick of a finger with a lancet. Diabetics consider this more painful than the actual injection of insulin. Obviously, they would prefer a less painful method and are willing to switch products to reduce their suffering. A solution to this problem may lie in noninvasive technologies. One company, Futrex Inc, has developed a prototype instrument named the Futrex 9000, which uses a modified pulse oximeter connected to a computing module. The patient inserts a finger into the instrument, and a near-infrared light directed through the finger measures the glucose concentration. Futrex is 1 to 2 years away from bringing the product to market.


L13 ANSWER 38 OF 38 EMBASE COPYRIGHT 1999 ELSEVIER SCI. B.V.
ACCESSION NUMBER: 85036518 EMBASE
DOCUMENT NUMBER: 1985036518
TITLE: Multivariate analysis in the **diagnosis** of liver disease and as an aid to optimal selection of serum enzyme tests.
AUTHOR: Goldberg D.M.; Ellis G.
CORPORATE SOURCE: Department of Biochemistry, Hospital for Sick Children, Toronto, Ont., Canada
SOURCE: Scandinavian Journal of Clinical and Laboratory Investigation, (1984) 44/SUPPL. 171 (113-129).
CODEN: SJCLAY
COUNTRY: Norway
DOCUMENT TYPE: Journal
FILE SEGMENT: 029 Clinical Biochemistry
048 Gastroenterology
017 Public Health, Social Medicine and Epidemiology
LANGUAGE: English
AB Computer-assisted classification of patients with hepatobiliary disease can be achieved using a **diagnostic algorithm** in the same population from which it was originally derived. When appropriate laboratory tests are selected,

the accuracy of decision-making by such a computer program can match that of experienced clinicians without requiring the detailed clinical information generally gathered and utilized by the latter. Serum enzyme and **immunoglobulin assays** seem to be particularly appropriate, especially when bilirubin and albumin concentrations are also included. It is important that all tests be carried out from the identical specimen, preferably at the earliest opportunity, since this will limit the secondary pathological processes modifying the biochemical changes due to the primary disease entity. Evaluation of the discriminatory role of each individual test has been carried out on a preliminary basis, but further refinements are necessary (and are in progress) to fine-tune the system and reduce the test profile according to statistically acceptable criteria. However, group selection strongly influences the accuracy of computer-assisted **diagnostic** procedures, so that discriminant functions derived from one clinical population cannot without careful validation and probable remodelling be applied to a second population.

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